PHARMA network® magazine
World CDMO News
N°58 - September 2023

Biotech
Biotech industry: between challenges and optimism

Finance
Big pharma's new life without Covid-19 products

Report
Medicines The Great Shortage: In search of solutions

Regulatory
EU Commission's proposed changes to marketing authorization procedures

CDMOs: Financial performance H1 2023

Pharmatis

Looking for user Friendly liquid unidose?

Stickpack is YOUR Solution

- Ready to use
- Practical to carry
- Easy to take

And Pharmatis YOUR Right Partner:

- Longstanding experience in development and formulation of liquid dosage forms
- Transposition from bottle or ampuls to stickpacks
- Analytic and regulatory support

Characteristics of the sticks:

- 4 to 20ml
- Width: 25 mm
- Pre-cut for easy opening

Contact us:
60190 Estrées-Saint-Denis – France
Tel : +33 (0)3 44 91 51 43 contact@pharmatis.fr **www.pharmatis.fr**

La FRENCH FAB

Connect with
PHARMAnetwork

Join us on social media
www.linkedin.com/
company/pharmanetwork

Contact PHARMAnetwork
info@pharmanerwork.com
redaction@pharmanetwork.com
advertising@pharmanetwork.com

Jean-Louis Briau-Geneste
Doctorate in Pharmacy,
Editorial Director
redaction@pharmanetwork.com

The importance of business strategy

In a complex global economic and macroeconomic context, coupled with various uncertainties, the growth of biologics development is an opportunity for the outsourcing industry.

An increasing number of more complex biomolecular formats are entering the global pipeline. These include bioconjugates, fusion proteins, recombinant proteins and bispecific antibodies (BsAbs). The resulting demand for services to develop and manufacture these complex biomolecules is expected to increase proportionately in coming years.

Leveraging extensive expertise and experience spanning the entire biologics development lifecycle, global BioCDMOs have deployed skills and capabilities strategically to establish integrated platforms that provide comprehensive end-to-end CRDMO services

Increasing complexity of molecules entering the clinical pipeline drives demand for experienced CDMOs who can help clients through development stages, reduce investment risk, and accelerate time to market as a critical contributor to competitive advantage.

Thanks to “Follow and Win the Molecule” strategies, major BioCDMOs (Lonza, Samsung biologics, Wuxi, Bioxcellence, etc.) continued to propel their growth in the first half of 2023.

Providing a very high level of customer service, based on mutual trust and respect, is a priority for BioCDMOs committed to respecting the highest standards of quality, meeting customer needs and patient safety.

Not being vigilant on a daily basis regarding strict compliance with quality standards can have disastrous effects and call into question the company's strategy at the highest level. This is the case of a major BioCDMO which is struggling with manufacturing problems in three factories and has announced a double-digit drop in its turnover for the last two half-years. Activist investors were quick to react by questioning of the company’s strategy. ■

CONTENTS

PHARMAnetwork magazine N°58

Our Commitment to Sustainability

Approvals

Biotech

To access more information click on the digital pictogram

M&A

Financial

Report

Regulatory

PHARMAnetwork magazine

is also available on PC, tablets and smartphones

The best of our journalism with full digital interactivity

including enhanced graphics, dynamic documents and editorial features

www.pharmanetwork.digital

N° 58 - SEPTEMBER 2023

PUBLISHER:
PHARMAnetwork Ltd
Becket House, 1 Lambeth Palace Road, London SE1 7EU, UK
www.pharmanetwork.com
info@pharmanetwork.com

EDITORIAL DIRECTOR:
Jean-Louis Briau-Geneste

EDITORS:
Jean Chaveroux, Luc Watson

CONTRIBUTING EDITORS:
Jean-François Hilaire; Stéphane Lepeu; Bruce Vielle; Carole Delauney; Javier Lopez-Belmonte; Sophie Vo; Sally Shorthose; Anna Koster; Hester Borgers; Sarah Faircliffe; Phillipus Putter; Nour Saab; Johanna Harelimana

PHOTO CREDITS:
Siegfried

COVER CREDITS: DR

TRANSLATOR:
Hancock Hutton, 26, rue Elisée Reclus – 33000 Bordeaux

ISSN NUMBER: 2102-1104

REGISTRATION OF COPYRIGHT: 3rd quarter 2023

A NOTE TO READERS:
The views expressed in articles are the authors' and not necessarily those of PHARMAnetwork magazine. Authors may have consulting or other business relationships with the companies they discuss.

LIBRARY ACCESS
Libraries offer online access to current and back issues of PHARMAnetwork magazine to: www.pharmanetwork.digital

SUBMISSIONS
We encourage prospective authors to follow PHARMAnetwork's "Guidelines for Authors" before submitting manuscripts.
To obtain a copy, Email to: redaction@pharmanetwork.com

TO WRITE TO US:
redaction@pharmanetwork.com

ADVERTISING:
advertising@pharmanetwork.com

PRINTING:
Manson - Reynolds House, 8 Porters Wood, Valley Road Industrial Estate, St Albans AL3 6PZ UK

2023 FDA approvals: 19 new medicines during Q2

During the second quarter of 2023, the FDA approved 19 new drugs (same level than during the first quarter of the year). At the end of the first six months of 2023, a total of 26 new medicines have been approved by the FDA (versus 16 in 2022 and 28 in 2021).

During Quarter 2 of 2023, the FDA approved thirteen new drugs, in a various range of diseases. The number of approvals was the same during the first quarter of 2023.

In the fields of **blood cancers**, the Food & Drug Administration gave the nod to two products. In May, it approved **Epkinkly (epcoritamab-bysp)** for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B cell lymphoma after two or more lines of systemic therapy. This product, manufactured by Genmab US, is injected subcutaneously (under the skin) in 28-day cycles until disease progression or unacceptable toxicity. Epkinly was approved under the accelerated approval pathway, under which FDA may approve drugs for serious conditions where there is an unmet medical need. In June, the FDA also granted accelerated approval to **Columvi (glofitamab-gxbm)**, developed by Genentech (Roche) for relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

In the fields of **Covid-19**, after one year of emergency use, Paxlovid manufactured by Pfizer got a full FDA approval. In May, the FDA gave the nod to the oral antiviral **Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use)** for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid was the fourth drug—and first oral antiviral pill—approved by the FDA to treat COVID-19 in adults.

In May, in the fields of **infectious diseases** and of antimicrobial resistance, the FDA approved **Xacduro (sulbactam for injection; durlobactam for injection)**, developed by Entasis Therapeutics. It is a new treatment for hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible strains of bacteria called Acinetobacter baumannii-calcoaceticus complex, for patients 18 years of age and older. Each year in the United States at least 2.8 million antibiotic-resistant infections occur, and more than 35 000 people die as a result.

In the fields of **women's health**, the FDA approved **Veozah (fezolinetant)**, an oral medication for the treatment of moderate to severe vasomotor symptoms (hot flashes), caused by menopause. It is the first neurokinin 3 (NK3) receptor antagonist approved by the FDA to treat moderate to severe hot flashes from menopause. Developed by Astellas Pharmaceuticals, it works by binding to and blocking the activities of the NK3 receptor, which plays a role in the brain's regulation of body temperature.

In the fields of **men's health**, the FDA approved the high-affinity radiohybrid (rh) Prostate-Specific Membrane Antigen (PSMA)-targeted PET imaging agent, **Posluma (flotufolastat F18) injection**. It is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis, who are candidates for initial

definitive therapy, or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. It is the first and only FDA-approved, PSMA-targeted imaging agent developed with proprietary radiohybrid (rh) technology. The product is manufactured by Blue Earth Diagnostics company.

In the fields of **central nervous systems diseases**, the FDA approved **Qalsody (tofersen)** in April to treat patients with amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase 1 (SOD1) gene (SOD1-ALS). Qalsody is an antisense oligonucleotide that targets SOD1 mRNA to reduce the synthesis of SOD1 protein. The approval was based on a reduction in plasma neurofilament light (NfL), a blood-based biomarker of axonal (nerve) injury and neurodegeneration. SOD1-ALS is a progressive neurodegenerative disease that attacks and kills the nerve cells that control voluntary muscles. Between 16,000 and 32,000 Americans are currently living with ALS. Approximately 2% of ALS cases are associated with mutations in the SOD1 gene; therefore, the agency estimates there are fewer than 500 patients with SOD1-ALS in the United States. Qalsody received an orphan drug designation.

MAs by FDA outsourced to contract manufacturers 2023 – Q2

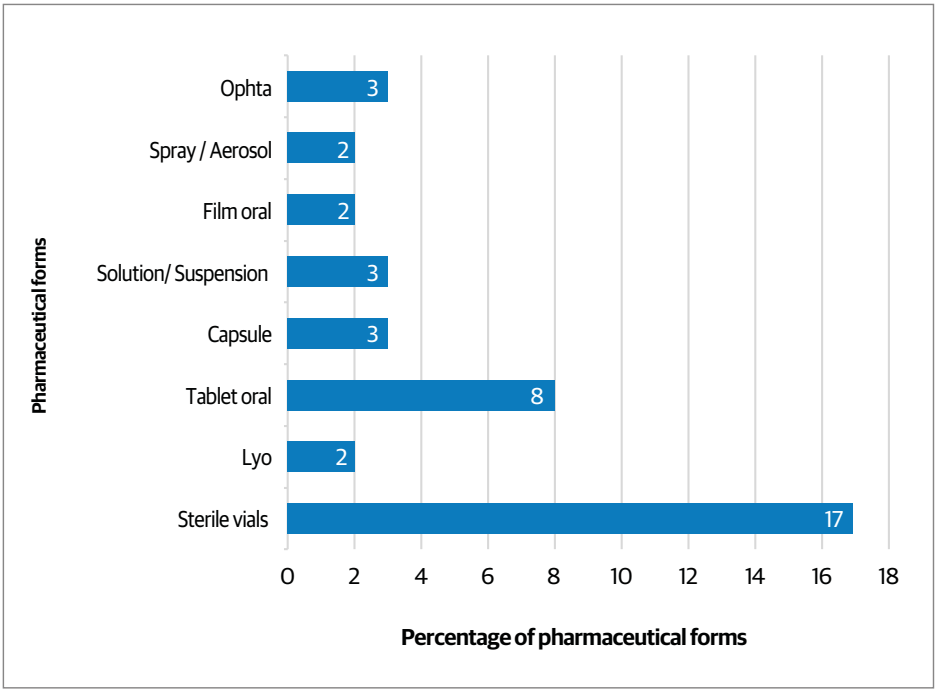
In the second quarter of 2023, only 13% of Original New Drug Application NDAs and BLAs authorized by FDA are Produced by CDMOs

• **Pharmaceutics International, Inc**. (Pii) is a US-based CDMO has been registred to produce Brixadi from Braeburn, Inc.. Brixadi is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. BRIXADI is a weekly and monthly injection provided in a pre-filled single dose syringe with a 23 gauge ½ inch needle.

Founded in 1994, Pii has grown from 12 employees to over 280 scientists and support staff and over 360,000 square feet of space in the U.S. Pii's GMP facilities are state-of-the-art and contain over 70 manufacturing rooms as well as containment suites for handling high potency compounds and hormones, dedicated manufacturing suites for oral products (e.g. soft gels) and injectables (e.g. vials and syringes), a formulation development center and state-of-the-art analytical laboratories.

• **Alliance Medical Products, Inc.** has been registered to produce Vevye.

ORIGINAL NDA AN ORIGINAL BLA APPROVALS BY FDA PHARMACEUTICALS FORMS 2023 – Q2)



Source: PHARMAnetwork studies

Vevye (cyclosporine ophthalmic solution) 0.1% is a calcineurin inhibitor immunosuppressant indicated for the treatment of the signs and symptoms of dry eye disease, packaged in multiple-dose eye drop bottles delivering single drops of approximately 0.01ml volume.

• In 2012, Swiss contract manufacturer **Siegfried** acquired Alliance Medical Products (AMP), based in Irvine, CA, USA for $58 million. This acquisition gives Siegfried, which is active in both the primary and secondary production of drugs, an entry into the custom market for sterile filling services.

As an internationally recognized outsourcing partner, Siegfried provides products and tailor made services that integrate seamlessly into a customer's value chain. The company offers pharmaceutical industry partners a comprehensive range of services - from development of drug

substances to product development, registration and manufacturing to packaging and logistics. Once a fully integrated pharmaceutical company, Siegfried is one of the few suppliers today that can provide both the drug substance and the drug product development and production capabilities. This combination of know-how and experience is unique for a supplier of development and production services.

Siegfried has expanded its technology base and geographic presence around the world in the past years. Its production facilities are located in Switzerland, the USA, Malta, China, Germany, France and Spain. In 2022, the company achieved net sales of CHF 1.2 billion and currently employs more than 3600 people.

SIEGFRIED'S IRVINE SITE

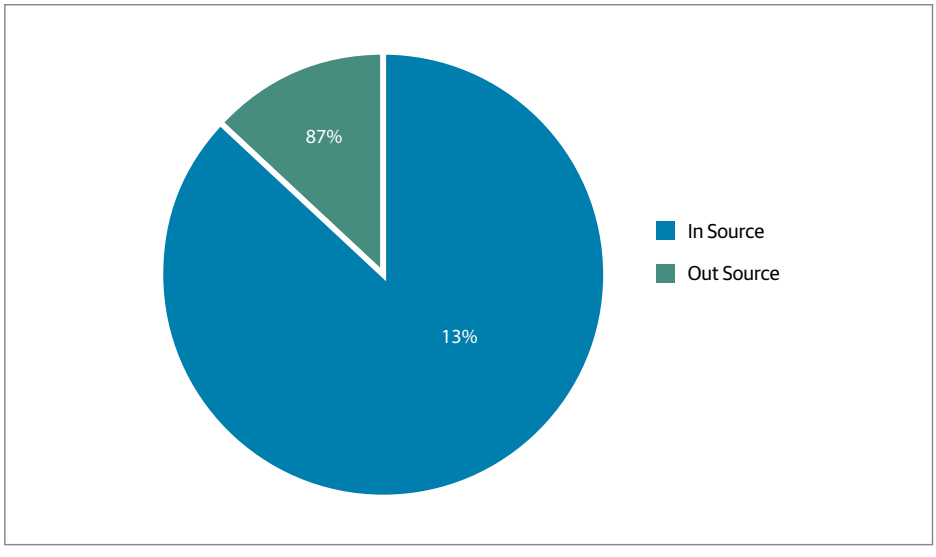
Source: Siegfried

• **Halozyme**, a biopharmaceutical company, has been registered to produce Vyvgart Hytrulo, a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients. Vyvgart Hytrulo injection is a preservative free, sterile, yellowish, clear to opalescent solution supplied as one single-dose vial per carton.

Halozyme is headquartered in San Diego, CA and has offices in Ewing, NJ and Minnetonka, MN. Minnetonka is also the site of its operations facility. Halozyme is the innovators of the ENHANZE® technology with the proprietary enzyme rHuPH20. Halozyme's commercially-validated solution is used to facilitate the delivery of injected drugs and fluids in order to reduce the treatment burden to patients. Having touched more than 700,000 patient lives in post-marketing use in six commercialized products across more than 100 global markets, Halozyme has licensed its ENHANZE® technology to leading pharmaceutical and biotechnology companies including Roche, Takeda, Pfizer, AbbVie, Eli Lilly, Bristol-Myers Squibb, Alexion, argenx, Horizon Therapeutics, ViiV Healthcare and Chugai Pharmaceutical.

Halozyme also develops, manufactures and commercializes, for itself or with partners, drug-device combination products using its advanced auto-injector technology that are designed to provide commercial or functional advantages such as improved convenience and tolerability, and enhanced patient comfort and adherence. ■

ORIGINAL NDA AND ORIGINAL BLA APPROVALS BY FDA OUTSOURCED TO CONTRACT MANUFACTURERS 2023 - Q2



Source: PHARMAnetwork studies

MAS BY FDA OUTSOURCED TO CONTRACT MANUFACTURERS 2023 - Q2

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Immediate Packaging	Submission Classification	Review Priority	Company	Manufactured by:
PACLITAXEL NDA #216338	PACLITAXEL	100mg/Vial	Powder; Intravenous	For injectable suspension: white to yellow, lyophilized powder containing 100 mg of paclitaxel formulated as albumin-bound particles in single-dose vial for reconstitution.	Type 5 - New Formulation or New Manufacturer	Standard	Teva Pharmaceuticals Parsippany, NJ 07054	**Pharmachemie B.V.** Haarlem, The Netherlands
PEMETREXED NDA #215179	PEMETREXED DISODIUM	Eq 100mg/10ml Base (10mg/Ml)	Solution; Intravenous	Injection: 100 mg/10 ml, 500 mg/50 ml, 1,000 mg/100 ml in single dose vials (3)	Type 5 - New Formulation or New Manufacturer	Standard	Shilpa Medicare Limited , India	**Zydus Lifesciences Limited** Ahmedabad, India
BRIXADI NDA #210136	BUPRENORPHINE	8mg/0.16ml (50mg/ml); 16mg/0.32ml (50mg/Ml); 24mg/0.48ml (50mg/ml); 32mg/0.64ml (50mg/ml); 64mg/0.18ml (356mg/ml); 96mg/0.27ml (356mg/ml); 128mg/0.36ml (356mg/ml)	Solution, Extended Release; Subcutaneous	Injection provided in a pre-filled single dose syringe with a 23 gauge ½ inch needle.	Type 3 - New Dosage Form	Priority	Braeburn, Inc., Plymouth Meeting, PA 19462, USA.	**Pharmaceutics International, Inc. (Pii),** Cockeysville MD 21030
VEVYE NDA #217469	CYCLOSPORINE	0.1%	Solution; Ophthalmic	VEVYE is a sterile, clear, colourless, non-aqueous, non-preserved ophthalmic solution packaged in multiple-dose eye drop bottles delivering single drops of approximately 0.01 ml volume. Each unit contains 2ml of VEVYE in a 5ml transparent squeezable polypropylene bottle with a transparent polyethylene tip and a white polyethylene cap with tamper-evident ring.	Type 5 - New Formulation or New Manufacturer	Standard	Novaliq GmbH, Heidelberg, Germany	**Alliance Medical Products, Inc. (DBA Siegfried Irvine),** 9342 Jeronimo Road, Irvine, CA 92618 (USA)
VYVGART HYTRULO BLA #761304	EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC	1008mg; 11200 Units Per 5.6ml	Injectable; Injection	A single-dose vial.			argenx US, Inc. 33 Arch Street Boston, MA 02110	argenx BV Industriepark 7 9052 Zwijnaarde, Belgium U.S. License No. 2217 **Halozyme Therapeutics, Inc.** 12390 El Camino Real San Diego, CA 92130 U.S. License No. 2187

European approvals in 2023: 11 new medicines in Q2

The European Medicines Agency approved 11 new medicines during the second quarter of 2023.

During the second quarter of 2023, 11 new medicines were approved by the EMA's human medicines committee (CHMP). It is ten less than during the first quarter.

Moreover, in February, the Committee recommended authorising the use of **COVID-19 Vaccine Valneva** (inactivated, adjuvanted) as a booster dose for adults 18 to 50 years of age.

• At its June meeting, it recommended two medicines. One against migraine, and another one against anemia. The committee recommended granting a marketing authorisation for **Aquipta (atogepant)**, developed by Abbvie Deutschland, for the prophylaxis of migraine in adults who have at least four migraine days per month. The active substance of Aquipta is atogepant, an analgesic which works as a calcitonin gene-related peptide (CGRP) antagonist. The benefit of Aquipta is that it reduces the number of migraine days per month, as observed in two phase 3. Approximately 15% of the EU population suffers from migraine. Atogepant was approved by the FDA under the name of Qulipta, in September 2021, and is available in the United States as the first and only oral calcitonin gene-related peptide (CGRP) receptor antagonist in the country, specifically developed for the preventive treatment of episodic migraine.

Jesduvroq (daprodustat), developed by GSK, received a positive opinion from the CHMP for the treatment of adult patients with anaemia associated with chronic kidney disease (CKD), a condition in which the kidneys are damaged and cannot filter the blood as well as they should. The Agency did not recommend authorising Jesduvroq for patients who are not on dialysis as there were insufficient data to establish its safety in these patients. As a result, GSK decided to withdraw the marketing authorisation application on 12 July. CKD is an increasing global health burden affecting 700 million patients worldwide, with an estimated one in seven patients also developing anaemia. In February 2023, the FDA approved Jesduvroq tablets for the once-a-day treatment of anaemia due to CKD in adults who have been receiving dialysis for at least four months.

• In May, the CHMP also recommended two new medicines for approval. The committee recommended granting a marketing authorisation for **Pylclari (piflufolastat F-18)**, developed by Curium Pet France, for the diagnosis of prostate cancer. The benefit of this medicinal product is its potential to diagnose prostate cancer during primary staging of patients at high risk, and in the staging of patients with a suspected recurrence. Piflufolastat F-18 was approved for medical use in the United States in May 2021.

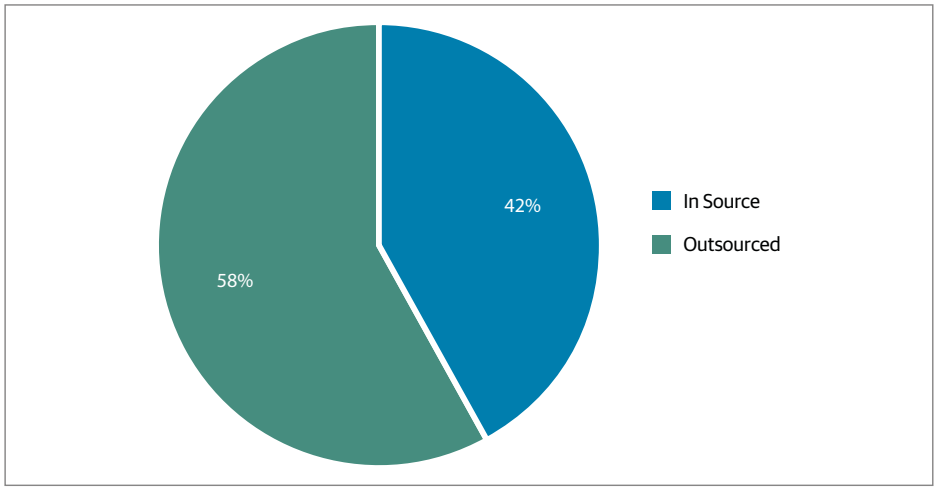
The committee also granted a positive opinion for **Ztalmy (ganaxolone)**, intended for the treatment of epileptic seizures associated with cyclin-dependent kinase-like 5 CDKL5) deficiency disorder (CDD), a genetic disorder defined by seizures in children and adolescents. The applicant for this product is Marinus Pharmaceuticals Emerald Ltd.

• April was the most dynamic month in terms of approvals, with seven new medicines recommended by the CHMP. Among the most important products, it recommended granting a marketing authorisation for **Arexvy (recombinant, adjuvanted)**, the first vaccine for active immunisation to protect adults aged 60 years and older against lower respiratory tract disease caused by respiratory syncytial virus (RSV). The European commission then in June, authorized GSK'S Arexvy. This is the first time an RSV vaccine for older adults has been granted European Marketing Authorisation. In Europe, RSV leads to over 270 000 hospitalisations and approximately 20 000 in-hospital deaths in adults 60 years of age and older each year, GSK explains. Arexvy was also approved in May 2023 by the FDA.

In cardiovascular disease, the CHMP gave a positive opinion for Camzyos (mavacamten), developed by BMS, for the treatment of symptomatic obstructive hypertrophic cardiomyopathy. In this disease, the heart muscle becomes thickened and makes it harder for the heart to pump blood.

In blood diseases, the CHMP gave two positive opinions in April. One for **Columvi (glofitamab)** under conditional marketing authorisation, for the treatment of diffuse large B-cell lymphoma (DLBCL), an aggressive type of non-Hodgkin lymphoma, a cancer of the lymphatic system that can arise in lymph nodes or outside of the lymphatic system. In July, the European Commission authorized the medicine developed by Roche. The CHMP also granted a positive opinion under conditional marketing authorization to **Jaypirca (pirtobrutinib)** for the treatment of relapsed or refractory mantle cell lymphoma (MCL). It develops when B-cells, a type of white blood cell that makes antibodies, become abnormal. The applicant for this medicinal product is Eli Lilly Nederland.

MAS BY EMA OUTSOURCED TO CONTRACT MANUFACTURERS 2023 - Q2



Source: PHARMAnetwork studies

MAs by EMA outsourced to contract manufacturers 2023 - Q2

In 2023 Q2, nearly 60% of new molecules registered by the EMA are subcontracted to CDMOs.

45% of drugs are sub-contracted by Irish companies, including two by Millmout Healthcare.

Founded in 1996, **Millmount Healthcare** in Ireland was acquired in 2017 by PCI Pharma services. PCI Pharma services has debuted a state-of-the-art dedicated high containment packaging facility specializing in commercial primary and secondary packaging for all solid oral dose forms including specialized and high potent products.

PCI has solidified leadership position in the EU with strategic investment to deepen presence in Ireland and expand its European foothold.

The Irish site was registered in 2023 Q2 for the production of two new drug approvals:

- Vafseo, Film-coated tablet packaged in blister (PVC/alu) for AKEBIA Europe
- Briumvi, Concentrate for solution for infusion conditioning in vial (glass) for Propharma Group.

The manufacturer of the biological active substance is Samsung Biologics Co., Ltd. Incheon site, South Korea

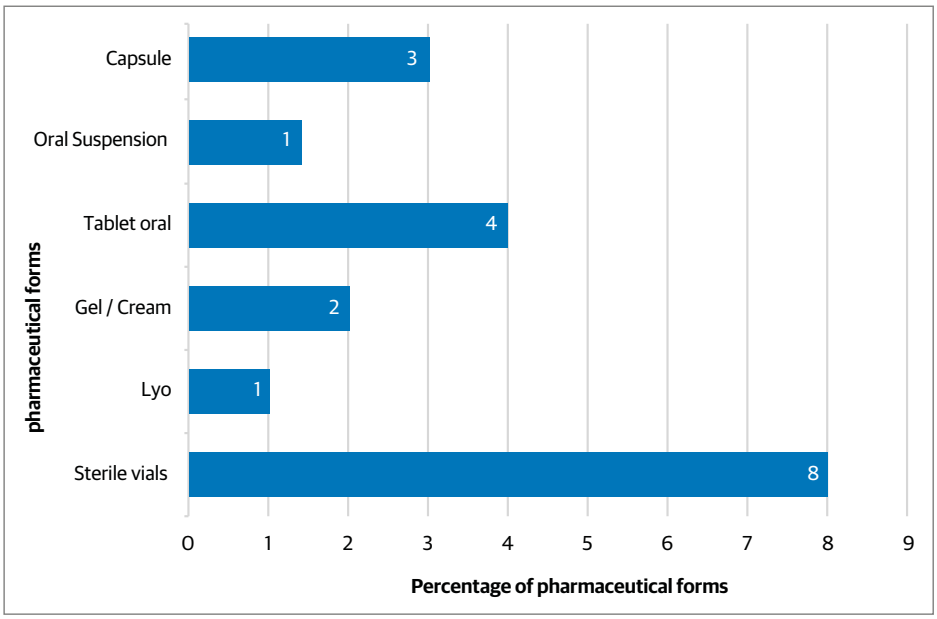
MSK Pharmalogistic GmbH, Germany is the manufacturer for Plusultra pharma GmbH, of Hyflor: Gel packaged in 10 gram tube. The three letters in MSK have been synonymous with outstanding services in the healthcare industry for more than 25 years. Since its establishment by the executive directors Klaus-Dieter and Marion Heß, MSK has successfully existed on the market as a medium-sized family business.

Patheon Biologics Australia Pty Ltd is the manufacturers of the biological active substance Eculizumab for Samsung Bioepis NL B.V. Netherland.

The Thermo Fisher Scientific site in Brisbane, Australia is a state of the art facility, specializing in clinical and commercial manufacturing, and single

use biologics technology: Mammalian cell culture manufacturing. Scale up and cGMP manufacturing of recombinant protein and monoclonal antibodies. The Brisbane facility won the ISPE "2014 Facility of the Year" for Process Innovation, and is part of Patheon global network of Biologics sites, which also includes St. Louis Missouri and Groningen, Netherlands. ■

EMA OUTSOURCED TO CONTRACT MANUFACTURERS 2023 - Q2



Source: PHARMAnetwork studies

EUROPEAN MEDICINE AGENCY - DRUG APPROVALS - MANUFACTURED BY CDMO - 2023 - Q2

Drug Name/Product number/International non-proprietary name	Pharmacotherapeutic group	Strength	Pharmaceutical form	Dosage Form / Route	Immediate Packaging	Pack size	Marketing authorisation holder/company name	Manufactured by:
Opfolda EMEA/H/C/005695 Active substance miglustat	Other alimentary tract and metabolism products	65 mg	Capsule, hard	Oral use	Bottle (HDPE)	1 Bottle	Amicus Therapeutics Europe Limited Block 1, Blanchardstown Corporate Park Ballycoolin Road Blanchardstown, Dublin D15 AKK1 Ireland	**Manufacturing Packaging Farmaca** Neptunus 12, Heerenveen, Netherlands, 8448CN
Hyftor EMEA/H/C/005896 Active substance Sirolimus	nc	2 mg/g	Gel	Topical	Tube (10g)	1 Tube	Plusultra pharma GmbH, Fritz-Vomfelde-Str. 36 40547 Düsseldorf Germany	**MSK Pharmalogistic GmbH** Donnersbergstraße 4 64646 Heppenheim Germany
Lacosamide Adroiq EEA/H/C/006047 Active substance lacosamide	Antiepileptics	10 mg/ml	Solution for infusion	Intravenous use	Vial (glass)	5 Vials	Extrovis EU Ltd. Pátriárka utca 14. 2000, Szentendre Hungary	**Pharma Pack Hungary Kft.** Vasút u. 13, Budaörs H-2040 Hungary
Epysqli EMEA/H/C/006036 Active substance Eculizumab	Immunosuppressants	300 mg	Concentrate for solution for infusion	Intravenous use	1 Vial (glass)	1 Vial	Samsung Bioepis NL B.V. Olof Palmestraat 10 2616 LR Delft The Netherlands	**Patheon Biologics Australia Pty Ltd** 37 Kent Street, Woolloongabba QLD 4102, Australia Samsung Bioepis NL B.V. Olof Palmestraat 10 2616 LR Delft, Netherlands
Elfabrio EMEA/H/C/005618 Active substance Pegunigalsidase alfa	Other alimentary tract and metabolism products	2 mg/mL	Concentrate for solution for infusion	Intravenous use	1 Vial (glass)	1 - 10 Vial	Chiesi Farmaceutici S.p.A. Via Palermo 26/A 43122 Parma Italy	**Protalix Ltd.** 2 Snunit St., Science Park, Carmiel 2161401, Israel Chiesi Farmaceutici S.p.A. Via San Leonardo 96 43122 Parma,Italy
Vafseo EMEA/H/C/005131 Active substance Vadadustat	Antianemic preparations	150 mg, 300mg, 450mg	Film-coated tablet O	Oral use	Blister (PVC/alu)	28 to 98 tablets	AKEBIA EUROPE Limited 70 Sir John Rogerson's Quay, Dublin 2 Co. Dublin, D02 R296 Ireland	**Millmount Healthcare Limited** Block-7, City North Business Campus, Stamullen, Co. Meath, K32 YD60 Ireland
Pedmarqsi EMEA/H/C/005130 Active substance Sodium thiosulfate		80mg/ml	Solution for infusion	Intravenous use	Vial (glass)	1 Vial	Fennec Pharmaceuticals (EU) Limited Block A, 5th Floor, The Atrium, Blackthorn Road, Sandyford, Dublin 18 Ireland	**MIAS Pharma Limited** Suite 2, Stafford House Strand Road Portmarnock Co. Dublin Ireland
Sugammadex Adroiq EMEA/H/C/006046 Active substance sugammadex sodium		100 mg/ml	Solution for injection	Intravenous use	Vial (glass)	10 Vials	Extrovis EU Ltd. Pátriárka utca 14. 2000, Szentendre Hungary	**Pharma Pack Hungary Kft** Vasút u. 13, Budaörs 2040 Hungary
Briumvi EMEA/H/C/005914 Active substance Ublituximab	Immunosuppressants	150 mg	Concentrate for solution for infusion	Intravenous use	Vial (glass)	1 Vial	Propharma Group The Netherlands B.V. Schipholweg 73 2316ZL Leiden The Netherlands	**Samsung Biologics Co., Ltd.** 300 Songo bio-daero Yeonsu-gu Incheon, South Korea 21987 **Millmount Healthcare** Block 7, City North Business Campus, Stamullen Co. Meath,Ireland K32 YD60
Camzyos EMEA/H/C/005457 Active substance Mavacamten	Other cardiac preparations	2.5 mg; 5 mg; 10 mg; 15 mg	Capsule, hard	Oral use	Blister (PVC/PCTFE/alu)	14 capsules ; 28 capsules	Bristol-Myers Squibb Pharma EEIG Plaza 254 Blanchardstown Corporate Park 2 Dublin 15, D15 T867 Ireland	**Swords Laboratories Unlimited Company** T/A Bristol-Myers Squibb Pharmaceutical Operations, External Manufacturing Plaza 254 Blanchardstown Corporate Park 2, Dublin 15, D15 T867 Ireland
Qaialdo EMEA/H/C/005535 Active substance spironolactone	Antihypertensives and diuretics in combination	10 mg/ml	Oral suspension	Oral use	Bottle (glass)	1 bottle + 1 oral syringe of 1 ml + 1 oral syringe of 5 ml + 1 bottle adaptor	Nova Laboratories Ireland Limited, 3rd Floor, Ulysses House, Foley Street, Dublin 1 D01 W2T2 Ireland	**Pronav Clinical Ltd.** Unit 5, Dublin Road Business Park, Carraroe, Sligo F91 D439 Ireland

Biotech industry: between challenges and optimism

In a new report on biotechnology in Europe and in the United Sates, the EY advisory company details where the industry stands after the pandemic.

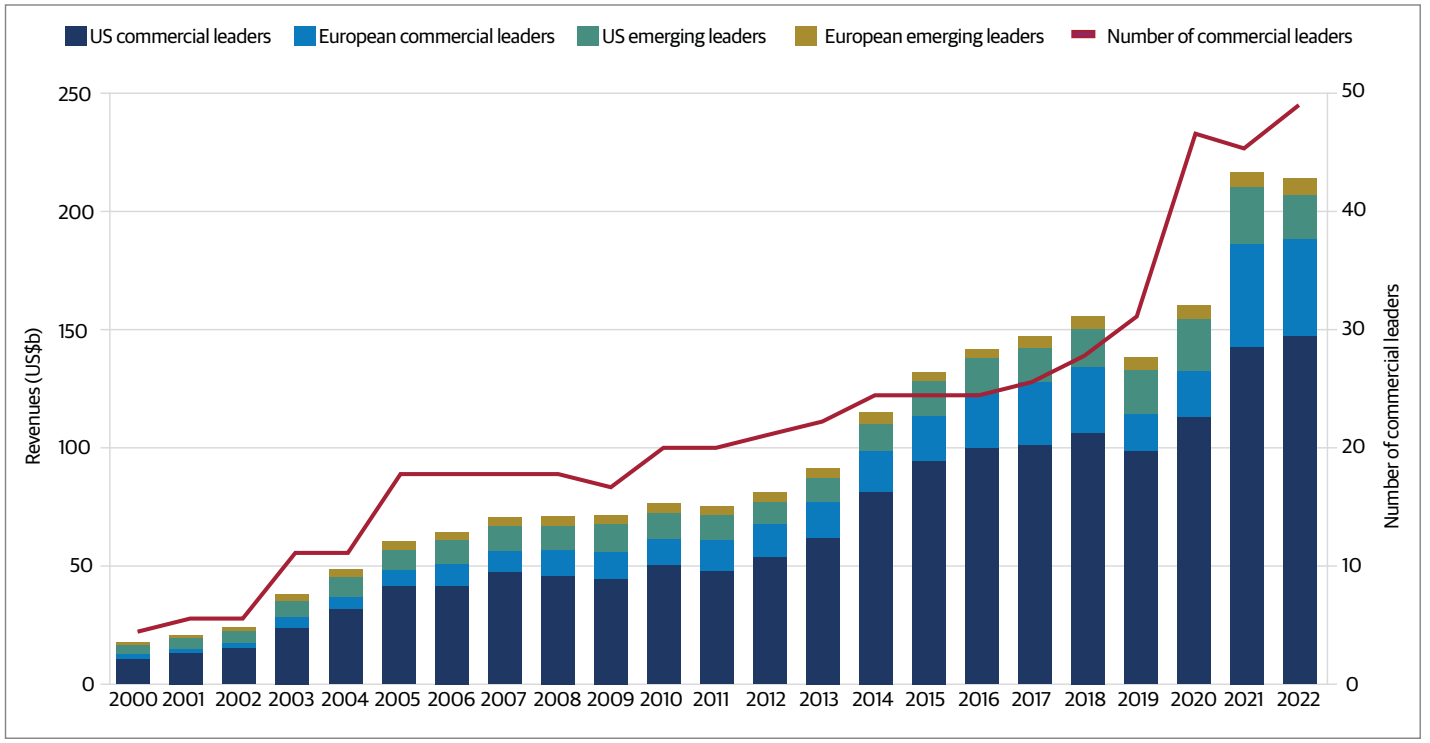
What is the economic situation of the biotech industry?

EY experts explain that "after a huge revenue surge in 2021 (+35 %), driven by the booming market for Covid-19 vaccines, therapies and testing, biotech's growth normalized in 2022". Total revenues of public biotech companies in the US and Europe stood at $215 billion in 2022 (-1%), due to declining demand for their Covid-19 vaccine and antiviral treatments. The change was almost entirely driven by fluctuations in demand for Covid-19 products (vaccines, antivirals...). "Without the revenue impact of Covid-19 products in the portfolios of five leading biotechs alone, the industry's revenues inched forward 3.7% in 2022, compared with 5.2% growth in 2021".

What is the main issue for the sector?

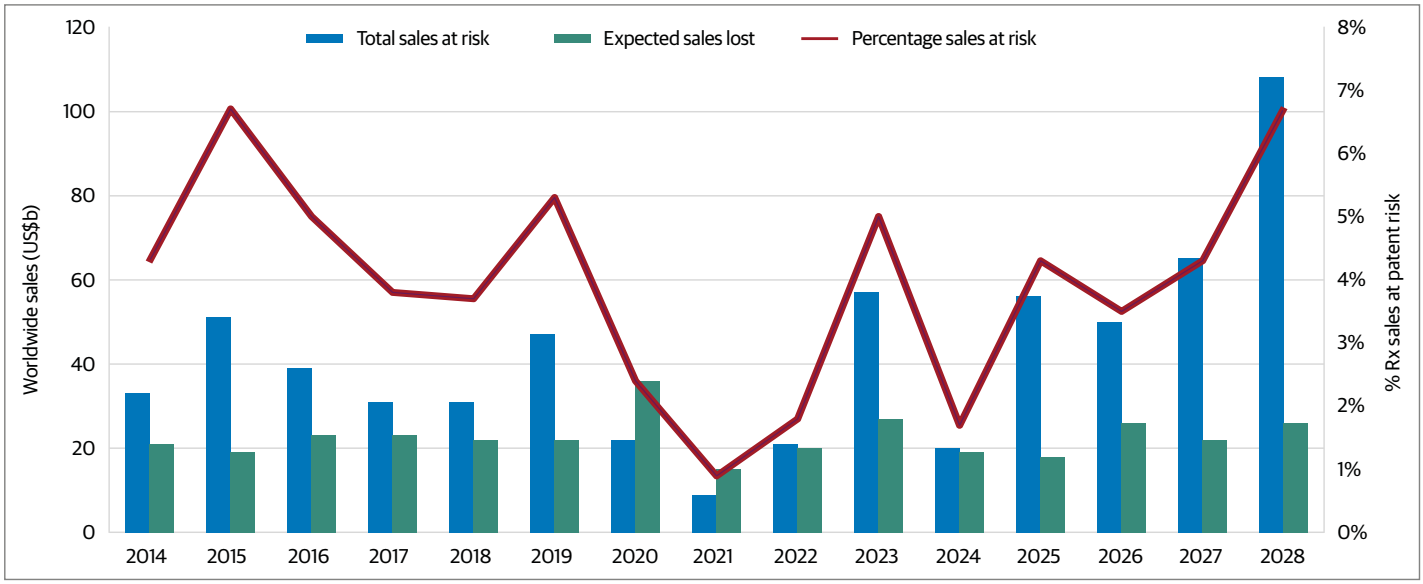
In the short term, the main challenge of the biotech industry definitely is the loss-of-exclusivity of several best-selling drugs. Early 2023 saw the US launch of Amgen's first biosimilar version of AbbVie's Humira (adalimumab). Four other blockbuster

FIGURE 1. US AND EUROPEAN PUBLIC COMPANY REVENUES, 2000-22



Source: IQVIA Survey of HCP (Oncologists and Immunologists) perception evolution on biosimilars, N=63.
Notes: HCP = Healthcare Professional.

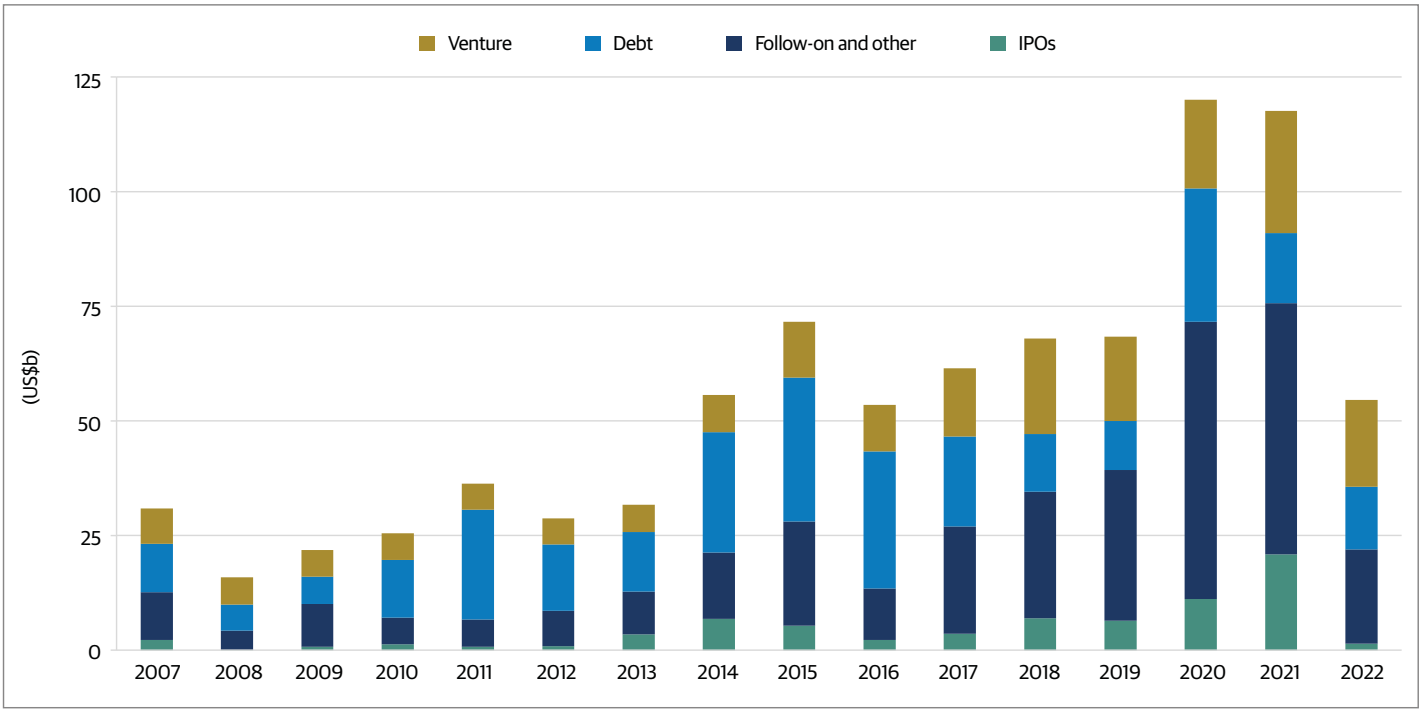
FIGURE 2. HISTORIC AND PROJECTED REVENUE EROSION THROUGH LOSS OF EXCLUSIVITY, 2014-28



Source: EY analysis, Evaluate Pharma (August 2022).
Total sales at risk refers to a product's annual revenue in the year before loss of exclusivity. Expected loss is the difference between that sales-at-risk number and the first full year of sales post expiry, as reported by companies for historic expiries or computed by Evaluate Pharma's consensus for those still to happen.

2022 saw a 54% annual decline in the levels of capital available to the biotech sector in the US and Europe

FIGURE 4. CAPITAL RAISED IN THE US AND EUROPE, 2008-22 (US$B)



Source:EY analysis, Capital IQ and Dow Jones VentureSource.

monoclonal antibodies (mAbs), with total revenues of over $14 billion in 2022, are also facing loss-of-exclusivity and biosimilar market competition by the end of 2023. The move will not end soon, as the next 5 years will see another 17 products, representing over $145 billion in annual revenues, lose their patent protection.

As a result, the industry is confronting an innovation deficit. It will be dependent on biotech's capacity to innovate and replenish lost revenues to sustain growth. The clinical pipeline contains over 20,000 active drug candidates around the globe. Moreover, multiple new therapeutic modalities with high clinical and commercial potential are rapidly reaching maturity. Cell and gene therapies are among the most prominent of the novel modalities, alongside new products developed through the mRNA platforms, new radiopharmaceuticals and the antibody-drug conjugates (ADCs).

What are the priorities of biotech companies?

The biotech industry is seeking "a new path forward", EY report says. "Biotech commercial leaders (companies with at least $500 million in annual revenue), along with their big pharma counterparts, are in dire need of addressing innovation deficits and in search of new revenues to offset the massive wave of pending patent expirations. On the other end of the spectrum, emerging biotechs face a capital-constrained operating environment and are wholly focused on getting to the next value inflection point with minimal cash burn".

After highly productive financing for the industry in 2020 and 2021 (with the industry raising nearly $240 billion in two years), 2022 saw a 54% annual decline in the levels of capital available to the biotech sector in the US and Europe. The $54.6 billion raised in 2022 represented the lowest annual investment in the industry since 2016.

According to EY analysts, "the biotech industry must navigate this complex path forward by driving efficient capital allocation and streamlining its core operations, from research and development to supply chain to commercial operations, while trying to maximize organic and inorganic growth through the use of M&A and alliances".

Biotech industry faces several headwinds at a time: reduced capital availability in a landscape of higher interest rates, tightening credit conditions, broader macroeconomic and geopolitical disruption, and a tougher regulatory environment (US Inflation

Reduction Act; increased scrutiny from the US Federal Trade Commission).

What does the future of biotechnology look like?

Despite these challenges, "the industry still maintains a favourable mid-to long-term outlook". Biotech remains in a position of strength, with a promising outlook for revenues, the unprecedented investments already made in the innovation renaissance in R&D, and a massive tide of dollars waiting for future attractive investments.

A "buyer's market" may emerge, with big pharma CEOs reconsidering targets that proved too expensive to justify the acquisition price in the past. Late-stage biotech assets that fit naturally into a company's strategic pipeline could become an M&A priority, and strategic alliances may remain "the preferred route" to access higher-risk early-stage innovation over outright bolt-on acquisitions.

"While some biotechs may struggle with reduced access to the public markets, the sector as a whole will continue to flourish as long as companies work to innovate to help address unmet medical needs of the future", EY report concludes, with a touch of optimism. ■

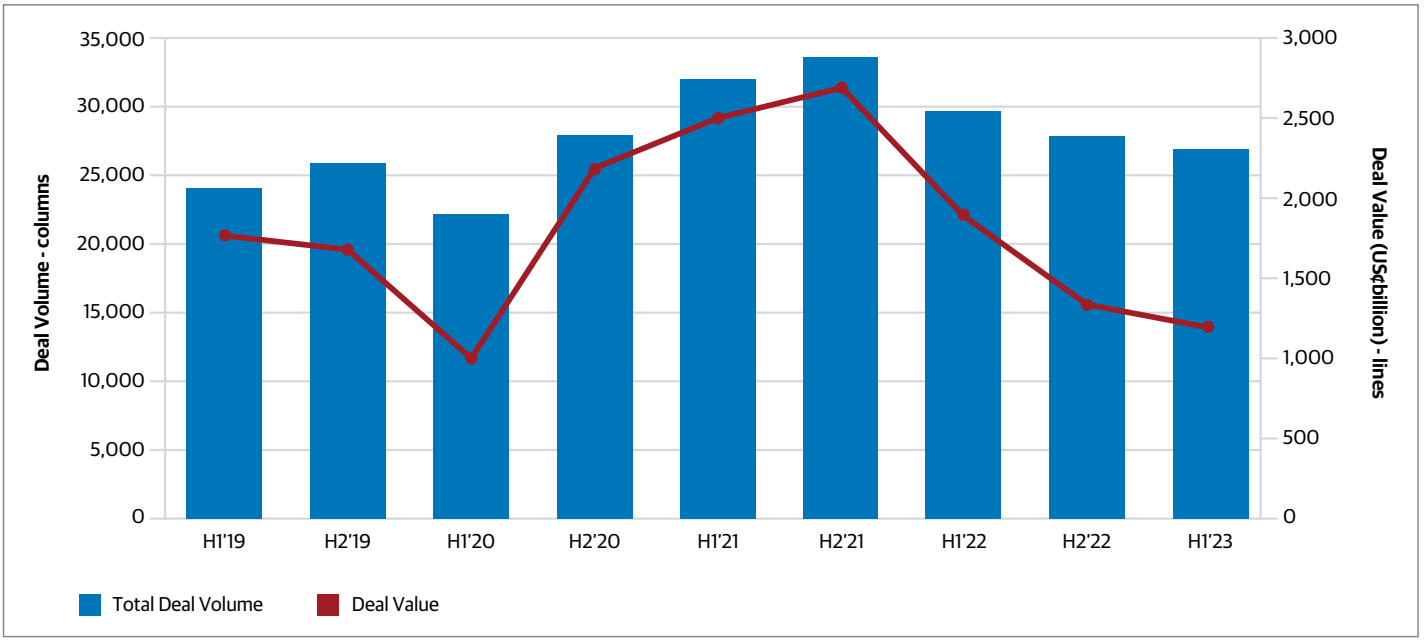
The M&A revival in 2023 Q2

Pharmaceuticals and life sciences (PLS) and healthcare services (HCS) continued to attract substantial investor interest, according to a PwC study. Meanwhile, deals volumes in all sectors declined by 4% during the first half of the year.

In terms of M&A, the first half of 2023 has been challenging for many dealmakers, with deal volumes declining by 4% (to 27 003 deals, totalling $1 208 billion), from already subdued levels in the second half of 2022. The number of deals of $1billion or more has declined by approximately 56% since the record M&A year in 2021. Deal volumes nonetheless remained above pre-pandemic 2019 levels, PwC experts explained in a special report dedicated to M&A trends. For the larger deals greater than $1billion in deal value, the decline was 11%. Deal volumes for deals less than $1billion declined by approximately 20% over the same period.

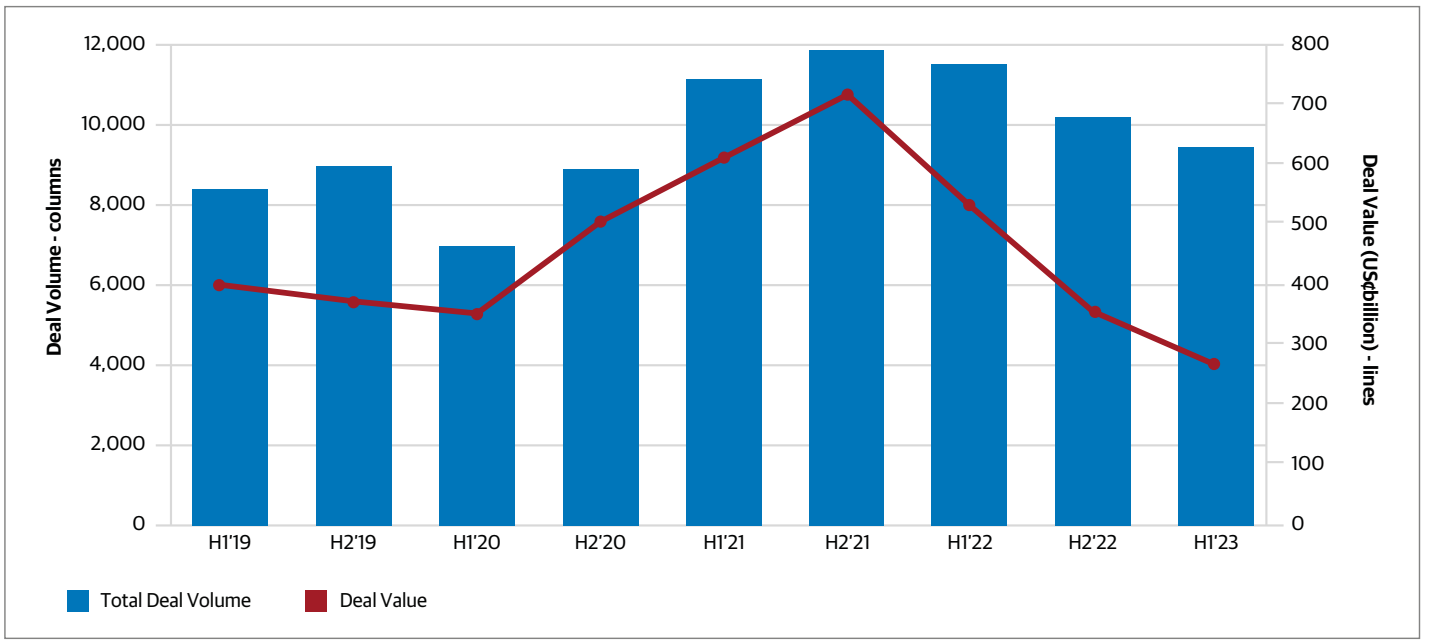
What about the second part of the year? According to PwC analysts, "deal flow could open up in the second half of the year, especially if sellers focus on pre-sale preparation and readjust expectations about pricing. But for many buyers, financing has become more difficult—and a lot more expensive. That is placing more emphasis on alternative funding and how to create value from a deal (-...) In our opinion, M&A is a more important growth driver today than in the recent past, and business leaders will be using it as a key tool to help them reposition their businesses, bolster growth and deliver sustained outcomes.

GLOBAL DEAL VOLUMES AND VALUES H1'19 - H1'23



Source: PWC analysis of capital IQ date

EMA - DEAL VOLUMES AND VALUES, H1'19-H1'23



Source: PWC analysis of capital IQ date

What type of company will likely drive the market? "We believe cash-rich corporates looking for strategic opportunities may be the deal stars for the remainder of the year and that mid-market M&A will dominate, with divestitures driving much of the deal pipeline", PwC analysts add.

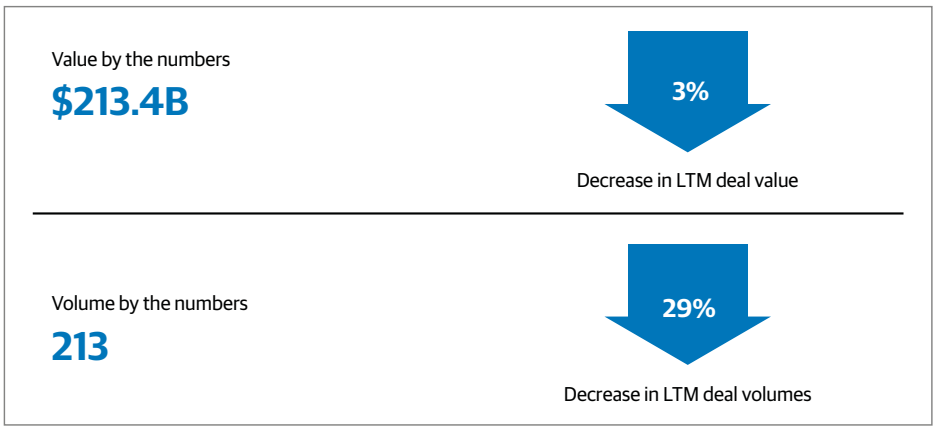
Focus on pharma industry

The advisory company PwC made a special focus on health industry. What were the main trends in the first half of 2023? Pharmaceuticals and life sciences (PLS) and healthcare services (HCS) continued to attract substantial investor interest. M&A remained a valuable transformation tool, even as increased antitrust scrutiny from regulators has made transformative mega-deals more difficult to complete. Large-cap pharma companies continued to pursue investments in mid-size biotech companies to bridge pipeline gaps, while portfolio reviews and divestitures of non-core assets remained top of mind. Private equity firms were eager to deploy their dry powder by acquiring innovative healthcare assets.

According to Stifel, an investment bank cited in the Financial Times," pharmaceutical and biotech companies spent $85 billion on acquisitions in the first five months of the year, marking a recovery in dealmaking as they seek to replenish drug pipelines. The surge in mergers and acquisitions, compared with $35.6 billion in deals in the same period of 2022 and $49.1billion the year before, is being fuelled by large cash reserves amassed by Big Pharma during the pandemic and investor concerns about growth prospects".

• Major pharmaceutical conglomerates were actively seeking M&A opportunities, including cross-border deals, to fill in their pipelines and achieve their growth plans as patents for many top-selling drugs are scheduled to expire in the back half

USA - DEAL VALUE LAST 12 MONTHS



*Source: PwC analysis of Capital IQ data. *Data from May 15, 2022 through May 15, 2023.*

of the decade. Regulatory scrutiny has already caused delays in some larger deals announced in the first half of 2023, prompting dealmakers to approach prospective transformative deals with caution.

• The combination of higher interest rates and lower stock prices has put additional pressure on corporate divestiture plans to free up capital for M&A. Large pharma companies, especially, were actively reviewing divestiture candidates to align strategic priorities and specialisations, mitigate upcoming patent expirations, and optimise portfolios.

• Private equity firms continue to show interest in contract research organisations (CROs), contract development and manufacturing organisations (CDMOs), and medtech companies. Declining public valuations present opportunities for public-to-private transactions in these sectors.

• Despite regulatory frictions, M&A activity in health industries should remain robust, with the potential for acceleration in the second half of 2023, as valuation gaps between buyers and sellers begin to narrow, and companies pursue innovative tech and AI-powered solutions to meet their strategic and operational challenges.

Concern over regulatory "scrutinity"

The M&A revival is threaten by the increased scrutiny of regulatory organisations. In May, the Federal Trade Commission sued to block Amgen's takeover of Horizon Therapeutics - a $28 billion deal announced in December-. According to the FTC, a "rampant consolidation" in the pharma sector was pushing up prices for patients. Amgen said it would fight this decision in court, but the industry fears that the action would chill M&A activity in the future. The FTC has also asked for more information on the deal between Pfizer & Seagen announced in Mars, worth up $43 billion.

FURTHER INFORMATION

M&A: PFIZER AND MERCK IN THE FOREFRONT

Main M&A in pharma in Q2 2023

• **In the United States**, in the last 12 months, deal value slightly declined. From May 15, 2022 through May 15, 2023, 231 deals were signed in the pharma industry (- 29%), totalling $213.4 billion (- 3%).

Immunology and oncology were two key therapeutic areas that have seen significant scientific breakthroughs in recent periods and have drawn interest from big pharma and biotech. These subsectors have also seen a resurgence of cross-border deals and a strong level of inbound M&A by foreign acquirers into the US market.

Despite recent declines in medtech deal volumes, dealmakers continued to look for targets that will accelerate the push towards patient-centric ecosystems and product-enabled services. Improving conditions such as higher procedure volumes, easing supply chain challenges and new technologies coming to market are likely to support increased M&A activity in the future.

In May, **Astellas Pharma** announced its intention to buy US biotech group **Iveric Bio** for roughly $5.9bn, giving the Japanese drugmaker access to the rapidly expanding market for treatments of age-related eye diseases. The acquisition will add ACP treatment to Astellas's portfolio. ACP is a treatment undergoing trials for geographic atrophy, an eye disease that affects 1.6mn patients in the US. Astellas, n°2 in Japan by revenue, has spent more than $7.3bn on overseas acquisitions and partnerships in recent years: in 2020, it spent $3bn to purchase US drugmaker Audentes Therapeutics and in 2010, $3.8bn to take over the oncology specialist OSI Pharmaceuticals.

• In Switzerland, **dsm-firmenich**, innovators in nutrition, health, and beauty, confirms, in July, the completion of its acquisition of Adare Biome, a pioneer in the development and manufacturing of postbiotics, as first announced on April 19 2023, for an enterprise value of €275 million. This transaction represents an estimated 2023 EV/EBITDA multiple of 18x.

Novartis has signed, in June, an agreement to divest 'front of eye' ophthalmology assets to Bausch + Lomb, a global eye health company, in a transaction valued up to USD 2.5 billion, including USD 1.75 billion in upfront cash, plus additional milestone payments. The deal includes Xiidra®, the first approved prescription treatment for the signs and symptoms of dry eye disease, and investigational medicine SAF312 (libvatrep), in development as a first-in-class therapy for chronic ocular surface pain (COSP), as well as the rights for use of the AcuStream delivery device in dry eye indications and OJL332, a second generation TRPV1 antagonist in pre-clinical development.

TOP 2023 PLS DEALS, YEAR TO DATE*

Transaction status	Target Name	Value of transaction ($ millions)	Acquiror full name	Industry
Announced	Seagen	44,551	Pfizer	Biotech
Announced	Provention Bio	10,955	Merck & Co,	Biotech
Announced	Syneos Health	7,502	Veritas Capital; Elliott Investment; Patient Square Capital	Other
Announced	IVERIC bio	6,024	Asetllas	Biotech
Announced	NuVasive	3,841	Globus Medical	Medical Devices
Closed	Provention Bio	2,881	Sanofi	Pharma
Announced	Polyplus-transfection SA	2,608	Sartorius Stedim Biotech S.A.	Biotech
Announced	BELLUS Health	1,971	GSK	Biotech
Announced	CTI BioPharma	1,746	Swedish Orphan Biovitrum AB	Biotech
Closed	Osstem impant	1,695	MBK Partners; Unison Capital Korea	Medical Devices

*Source: PwC analysis of Capital IQ data. *Data as of May 15, 2023*

CDMOs continue to attract substantial investor interest

Large pharmaceutical will continue to reshape their portfolios and identify non-core assets to divest. Since the May announcement of **Baxter** diving its biopharma business for $4.25 billion (PHARMAnetwork magazine May Issue), M&As and CDMO refinancings have been sparse in recent months. Macroeconomic conditions, rising energy costs and tighter funding have created an environment where transaction processes are taking longer, with more uncertain outcomes, more complex business cases and the need for deeper due diligence. However, declining valuations present opportunities for transactions in this sector.

With an increasing demand for novel therapeutics, the global CDMO biologic market was estimated to increase from $1.3 billion in 2021 to $3.1 billion in 2030, according to Prescient & Strategic Intelligence. Companies with mRNA or cell and gene therapy capabilities that continue to attract investors:

NewBiologix, a biotech startup founded by industry veterans Igor Fisch and Nicolas Mermod, announced a USD 50 million Series A funding round. The funding round, led by Recipharm A/S, will allow NewBiologix to begin beta testing prototype cell lines by 2024. They plan to make viral production cell lines commercially available by 2026. Based in Lausanne, Switzerland, NewBiologix SA is a technology innovation company developing a proprietary and breakthrough DNA integration platform for the advanced engineering of human and mammalian cell lines. NewBiologix is poised to help partners address an array of rare, chronic, and incurable diseases by filling the innovation gap to meet the surging demand for economically viable, large-scale production of viral vectors for gene therapy.

Ascend Gene & Cell Therapies (Ascend), has launched, in May, as a facilitator for gene therapy companies to help translate product ideas into viable clinical programs. Originally founded by Monograph Capital, Ascend Gene & Cell Therapies has raised a total of $132.5 million completing a Series A fundraise led by Abingworth and Petrichor, supported by DCVC Bio,

4BIO Capital, Cathay Health, Deerfield Management, Digitalis Ventures and Ajinomoto Co., Inc. Ascend's operations are headquartered in the UK with GMP production in Potters Bar, North London, platform technology research in the San Francisco Bay Area, USA, and a specialist process development and analytics team in Munich, Germany.

• In July, **Kincell Bio**, a CDMO focused on cell therapies, has emerged from stealth with $36 million in new funding. Kineticos Ventures led Kincell's launch funding. Kincell is a spinout of Inceptor Bio's CMC, manufacturing and quality organizations formed to accelerate innovator research and clinical trials. Kincell acquires a facility and a fully staffed team based at its Gainesville site, with plans to grow in Gainesville, as well as in additional key markets, such as Research Triangle Park (RTP), Boston and other customer locations.

Kincell offers analytical development, process development, CMC consulting and early-stage GMP manufacturing focusing on immune cell therapies, including autologous and allogeneic Chimeric Antigen Receptor (CAR)-T, CAR-NK and CAR-M programs. The Company plans to establish in-house mRNA development and additional GMP manufacturing capacity while forging trusted partnerships for viral vector and plasmid DNA supply to support all cell engineering processes.

What future for European SPACs

A Special Purpose Acquisition Company (SPAC) is an investment vehicle without operating activity, introduced on the stock market to acquire an unlisted company in a given sector and time frame. A SPAC generally has two years to identify an acquisition opportunity that could be approved by shareholders. Otherwise, it must return the funds to the investors.

SPACs have now lost their appeal. They do not find a company to buy, within the time allowed, and reimburse the investors.

Pegasus Europe, the SPAC launched in 2021 by Financière Agache, Tikehau, Jean-Pierre Mustier and Diego De Giorgi, announced its liquidation in April 2023. It could not find a company to buy at an acceptable price and preferred to return the money to investors. The failure of the largest European SPAC actually reveals the loss of interest and credibility suffered by these investment vehicles since their popularity in 2021. The end of free money signals the end of SPACs in the United States.

• In May 2022, **eureKING**, the first European SPAC in the health sector dedicated to bioproduction, was listed on the professional compartment of the regulated market of Euronext in Paris.

The eureKING SPAC was founded by a team from the health sector, composed of Michael Kloss, former President and CEO of Panasonic Healthcare, Gérard Le Fur, former CEO of Sanofi, Alexandre Mouradian, co-founder and administrator of eureKARE , Christophe Jean, strategic partner of the Private Equity fund Oraxys Environment, Hubert Olivier, President for France and Belgium of the pharmaceutical distribution and health services group McKesson and Rodolphe Besserve, CEO of eureKARE.

With a fundraising of 150 million euros in May 2022, eureKING aims to create a European bio-CDMO company listed on Euronext Paris. eureKING has chosen to focus on three highly specialized and strategic segments of the biopharmaceutical industry: the production of biological products, in particular new generations of monoclonal antibodies or complex proteins, the production of cell and gene therapies and the production of live biotherapeutic products.

On May 16, 2023, just one year after its market introduction, EureKING announced the signing of a put option for the potential acquisition of Skyepharma, CDMO specialized in oral solid forms, with specific expertise and proprietary technologies on modified release products. Skyepharma is based in Saint-Quentin-Fallavier, France. The current factory is dedicated to its activity, occupies 22,000 m², on a plot of 60,000 m².

This first acquisition is quite unexpected for a SPAC aiming to create a European bio-CDMO company!

However, Skyepharma has launched, in order to enhance its land and its quality expertise, an offer of turnkey premises and support for biotechs looking for means of production. MaaT Pharma is the first tenant of SkyePharma's SkyeHub. SkyePharma is financing the construction of a 1,500m² building - the area of which can be doubled - meeting cGMP standards, while providing MaatPharma with its expertise in quality, regulatory affairs, certification and large-scale production. MaaT Pharma brings its own teams and equipment to control and supervise the R&D as well as the clinical and commercial production of its complete ecosystem microbiota-based biotherapies.

The proposed eurKing transaction would value Skyepharma at an enterprise value of approximately €50 million and an equity value of approximately €52 million. On May 25, 2023, EureKING announced a put option contract relating to 100% of the capital of Oleron Pharma, a holding company owning 100% of Skyepharma.

Although with a SPAC merger there is a degree of flexibility in negotiating certain terms with the SPAC sponsors, including valuation, this should not fall far short of the level the public markets are willing to pay. If valuations are perceived to be too high once stocks go public, chances are the stock will under perform, as many de-SPAC companies have done in the past.

The proposed transaction would be the first step in eureKING's plan to add innovative companies to its platform and thereby create a leader in the bio-CDMO sector.

At the beginning of August 2023, eureKING announced the acquisition of 100% of **SCT Cell Manufacturing s.r.o.**, bioCDMO covering GMP production of Advanced Therapy Medicinal Products including genetically modified and viral vectors. SCTbio leverages a decade of experience in development of autologous cell-based products, product supply for clinical trials, GMP compliance for the full lifecycle of drug development, manufacturing, quality control, and process development services.

This second acquisition is more in line with euroKing's strategy of ultimately creating a European bio CDMO. EureKING would acquire from SCTbio for a cash sum of approximately €13.08 million, 67% of the shares of SCTbio held by PPF, the sole shareholder of SCTbio. The remaining 33% - currently owned by PPF Biotech - will be settled through newly issued shares of eureKING, after which the French SPAC will fully own SCTbio.

SCTbio has a 2000m² cell and gene therapy production site where its team produces both cellular products such as CART cells and viral vectors. SCTbio is able to produce different products based on immune cells (Treg and Gamma Delta T-cells), but also retroviral and lentiviral vectors.

There is still a long way to go for SPAC EureKING to achieve the status of a European-scale bioCDMO and compete with market leaders.

Sequens enters the cell and gene therapy segment

The Swiss laboratory Novartis announced on July 20 that it was in exclusive negotiations with the French pharmaceutical company Seqens to sell its cell therapy factory CellforCure located in Les Ulis.

This acquisition would allow Seqens to fully enter the cell and gene therapy segment. Novartis was looking for a buyer for this bioproduction site, specializing in CAR-T treatments. By finalizing this operation, Seqens would begin a strategic shift towards the manufacture of cell and gene therapies. The production of CAR-T therapies is particularly complex because each dose is tailor-made for each patient, from samples of their own blood cells. They are then genetically modified in the laboratory and cultured in vitro before being reinjected into the patient: they will continue to multiply by binding to the targeted cancer cells and eliminating them.

Novartis had acquired CellforCure from LFB in December 2018, one of the first and largest contract development and manufacturing organizations (CDMO) producing cell and gene therapies in Europe. Established as a pharmaceutical company since 2013, CellforCure operates a Contract Development and Manufacturing Organization. The company obtained two Good Manufacturing Practice (GMP) certificates from the French National Agency for the Safety of Medicines and Health Products (ANSM) in 2016 for the production of innovative experimental and commercial therapy drug.

Valneva divests its clinical trial manufacturing to North X Biologics

• In July, **NorthX Biologics**, a leading Nordic development and manufacturing organisation with a focus on advanced biologics, CGT (cell and gene therapy) and vaccines, has acquired the Stockholm-based Clinical Trial Manufacturing unit from Valneva Sweden.

The acquisition includes the transfer of a multi-purpose facility, situated in the Stockholm life science cluster, close to Karolinska University Hospital. In addition, 30 staff members who currently operate the facility will also join NorthX. The site and staff have a long history with extensive experience of serving both Valneva internally and also working with external customers on a contract development and manufacturing basis. With expertise in mammalian expression systems and viral vectors, the capabilities complement those of NorthX's existing business of advanced microbial based manufacturing of proteins and plasmid DNA. The acquired unit excels in process development, scale up, GMP production, quality control analytics, and quality assurance/release and is capable of working with Biosafety Level (BSL) 2/2+ and BSL 3 organisms. With this expansion, NorthX enhances its capabilities and can offer comprehensive services to a wider range of clients globally.

CorEvitas will become part of Thermo Fisher's Laboratory Products and Biopharma Services segment

• In August **Thermo Fisher Scientific Inc.** has completed the acquisition of CorEvitas, LLC, a leading provider of regulatory-grade, real-world evidence for approved medical treatments and therapies, from Audax Private Equity, for $912.5 million in cash. Thermo Fisher announced the agreement to acquire CorEvitas on July 6, 2023.

CorEvitas expands Thermo Fisher clinical research business with highly complementary real-world evidence solutions, which is an increasingly important area and will help to enhance decision-making as well as the time and cost of drug development. ■

GENERIS

POS

AMERICAN PHARMA MANUFACTURING & OUTSOURCING SUMMIT

WESTIN COPLEY, BOSTON | OCTOBER 9-10, 2023

KEY SPEAKERS

LUIS ROMAN

VP, SUPPLY CHAIN, SMALL MOLECULES GLOBAL PLATFORM

janssen

KARIN ANN PAYNE

VP, QUALITY ASSURANCE

BAYER

IMARA CHARLES

VP, PROCESS AND DIGITAL EXCELLENCE, GLOBAL SUPPLY CHAIN

Bristol Myers Squibb

LARRY PUDERBACH

AVP, RESEARCH QUALITY

MERCK

RESERVE YOUR SPOT

posummit.com

The 7th annual American Pharma Manufacturing & Outsourcing Summit connects executives from leading pharma organizations to network, share insights, and collaborate on fresh solutions in pharmaceutical manufacturing, external quality, supply chain management, and more.

Interested in learning from the industry's thought leaders or showcasing your solutions?

120+ PHARMA LEADERS	**60+** EXECUTIVE SPEAKERS	**50+** SPEAKER SESSIONS	**40+** SOLUTION PROVIDERS

WORLD VACCINE CONGRESS EUROPE

16-19 OCTOBER 2023 | FIRA DE BARCELONA

R&D + STRATEGIC PARTNERING FOR THE GLOBAL VACCINE INDUSTRY

REGISTER WITH CODE PNET20 FOR 20% OFF TICKETS

2000+ ATTENDEES

250+ SPEAKERS

125+ EXHIBITORS

SCAN ME

CONFERENCE TRACKS INCLUDE

BIOPROCESSING MANUFACTURING

NEW TECHNOLOGY

ANTIMICROBIAL RESISTANCE

INFLUENZA & RESPIRATORY

IMMUNOONCOLOGY

EMERGING & RE-EMERGING

WORKING WITH

GSK

BIONTECH

moderna

Pfizer

janssen

sanofi

SPONSORS INCLUDE

EMERGENT

eppendorf

SARTORIUS

PANELS FEATURING IN OUR CONTENT-LED AGENDA

HOW ARE WE IMPROVING RNA VACCINE TECHNOLOGY?

Prof. Jeffrey W. Almond
Visiting Professor of Microbiology
University of Oxford

Dr Andreas Kuhn
SVP, RNA Biochemistry & CMC Development
BioNTech

Dr Jacqueline Miller
SVP, Therapeutic Area Head - Infectious Disease Development
Moderna

Dr Sudha Chivukula
AVP, Head of Discovery Biology, mRNA Centre of Excellence
Sanofi

Dr Dennis Christensen
Head of Global Research & Development Adjuvant Systems
CRODA

CAN WE BUILD GLOBAL VACCINE PRODUCTION CAPACITY IN TIME FOR THE NEXT PANDEMIC?

Anjalee Khemlani
Senior Reporter
Yahoo! Finance

Dr Martin Friede
Unit Head of the Product & Delivery Research team (PDR) for the Department of Immunization, Vaccines and Biologicals
WHO

Rajinder Suri
CEO
DCVMN

Akhona Tshangela
PAVM coordinator
Africa CDC

Prof. Petro Terblanche
CEO
Afrigen

MOVING TOWARD GLOBAL REGULATORY ALIGNMENT

Dr Laura Viviani
Consultant
Former DCVMN

Parag Nagarkar
Head of Regulatory Affairs
Serum Institute of India

Mic McGoldrick
CMC Technical Advocacy & Policy
MSD

Rosane Cuber Guimaraes
Deputy Director Quality
FioCruz

Catherine Milne
Head of Section Biological Standardisation
EDQM

Maria Fernanda Reis e Silva Thees
Health Surveillance Specialist
Anvisa

Big pharma's new life without Covid-19 products

Is there a future without Covid-19 products? Drugmakers gave a clear answer to the market, while announcing their results for the second quarter and the first half of 2023.

During the first half of 2023, several giant drugmakers faced one main challenge: how to maintain growth without Covid-19 products that delivered huge profits one year ago? Moreover another challenge concerned almost all pharmaceutical companies: blockbusters portfolios competing with biosimilars and generics. The financial results clearly reflected this dilemma, even if many companies have raised their global outlook for the year.

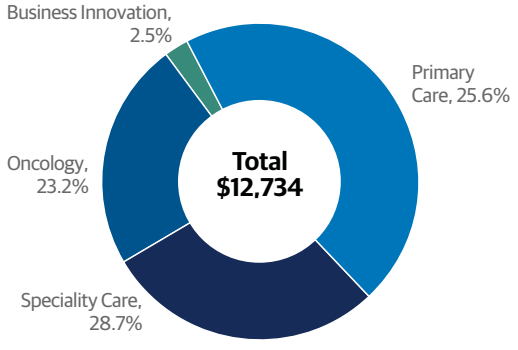
Pfizer fights to grow without Covid-19 products

During the second quarter of 2023, Pfizer delivered a 5% operational revenue growth, excluding its Covid-19 products and announced that its year-to-date results were in line with expectations. "Despite a few near-term individual product revenue challenges, we believe the company is well positioned for accelerated growth of our non-Covid products in the second half of 2023", David Denton, Chief Financial Officer and Executive Vice President, said.

Profits in the second quarter were $2.3 billion, down 77% as revenues fell 54% to $12.7 billion. Quarterly revenues for Pfizer's Covid-19

PFIZER - Q2 2023 SUMMARY FIGURES

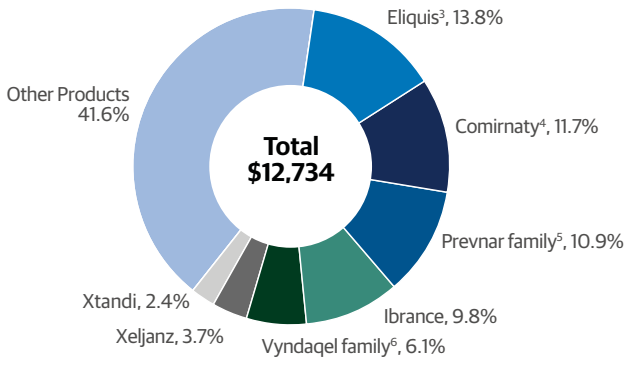
Revenue by Customer Group[1] ($M)



% Operational Growth

Primary Care	Specialty Care	Oncology	Business Innovation[2]	Total
-82%	-1%	-4%	43%	11%

Top 7 Products by Revenue[1] ($M)



% Operational Growth

Eliquis[3]	Comirnaty[4]	Prevnar family[5]	Ibrance	Vyndaqel family[6]	Xeljanz	Xtandi
2%	-82%	-1%	-4%	43%	11%	5%

Source: Pfizer

1. Product percentages are calculated using total company revenue as denominator. 2. Business Innovation is an operating segment established in Q1 2023 that includes Pfizer CentreOne, the company's global contract development and manufacturing organization and a leading supplier of specialty active pharmaceutical ingredients, and Pfizer Ignite, a recently launched offering that provides strategic guidance and end-to-end R&D services to select innovative biotech companies that align with Pfizer's R&D focus areas. 3. Eliquis alliance revenues & direct sales. 4. See Slides 34-35 for definitions. 5. Prevnar family includes revenues from Prevnar 13/Prevenar 13 (pediatric and adult) and Prevnar 20/Apexxnar (pediatric and adult). 6. Vyndaqel family includes global revenues from Vyndaqel, as well as revenues for Vyndamax in the U.S. and Vynmac in Japan.

vaccine and Paxlovid therapeutic were $1.6 billion, far below the $16.9 billion in the year-ago period. For the first six-month of 2023, Pfizer announced revenues down 42% to $31 billion, whereas reported net income stood at $7.8 billion (-56%).

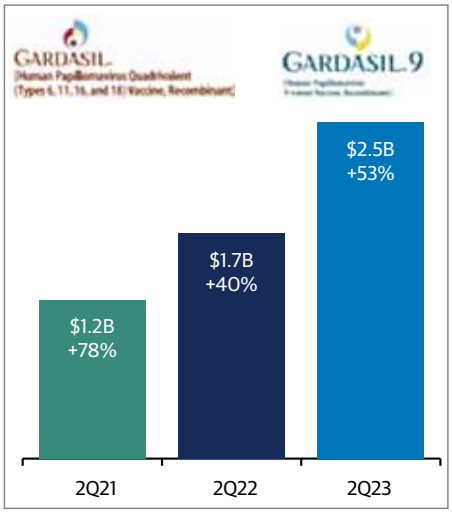
Company revenues are anticipated to be lower in 2023 than in 2022 due to expected revenue declines for Pfizer's Covid-19 products. A decline partially offset by expected operational growth from its non-Covid-19 in-line portfolio, anticipated new product and indication launches and recently acquired products. Excluding Covid-19 products, Pfizer now expects 6% to 8% operational revenue growth in 2023. That's down 1% from the prior range. The company also narrows its 2023 revenue guidance range to $67 to $70 billion.

Pfizer said its acquisition of biotech company Seagen remains on track. The company is in touch with regulators and expects the deal to close in late 2023 or early 2024. In order to build growth out of Covid-portfolio, Pfizer indicated it made significant progress toward its goal to launch 19 new products and indications in an 18-month span, having executed eleven launches thus far. According to analysts, this challenge is amazing, compared to its usual rate of launches of one or two new products per year. Pfizer emerges on the market as the most promising healthcare stock on the list, from a fundamental analysis perspective.

Merck tops expectations and raises its annual outlook

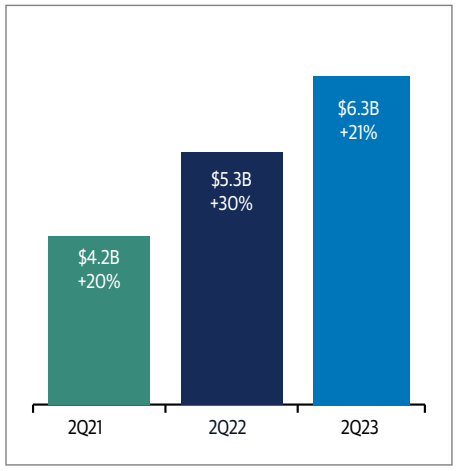
Merck reported second-quarter revenue that topped expectations, at $15 billion, an increase of 3% the same period of 2022, on strong sales of its blockbuster cancer drug Keytruda (19% to $6.3 billion) and HPV vaccine Gardasil (47% to $2.5 billion).

MERCK - KEYTRUDA



Source: Merck

MERCK - ONCOLOGY: KEYTRUDA CONTINUES TO DRIVE STRONG GROWTH



Source: Merck

But the pharmaceutical giant posted a quarterly loss due to its acquisition of the biotech company Prometheus Biosciences earlier this year, which will accelerate the company's growing presence in immunology. The loss income stood at $5.9 billion versus a net income of $3.9 billion in 2022.

For the first half of 2023, Merck announced global sales of $29.5 billion (-3% compared with the same period in 2022) and a loss income of $3.1 billion versus a net income of $8.25 billion in 2022.

Merck continues to experience strong global demand for key growth products, particularly in oncology and vaccines. As a result, it is raising and narrowing its full-year sales outlook, with full-year sales to be between $58.6 billion and $59.6 billion. This full-year outlook includes approximately $1 billion of Lagrevio sales (treatment against Covid-19).

Amgen still confident to purchase Horizon Therapeutics

Amgen had a very positive Q2, with total revenues increased 6% to $7 billion in comparison to the second quarter of 2022, resulting from a 6% increase in product sales. Net income stood at $1.37 billion, up 4,71%.

Volume growth was driven by Evenity (47% to a record $281 million), Blincyto (48% to $206 million), Repatha ($424 million, + 30%), Lumakras/Lumykras ($77 million) or Vectibix ($248 million, +28%), in the fields of general medicine, hematology or oncology.

For the first half 2023, Amgen announced global sales of $13 billion (+2%), with net income of $4.22 billion (+51%). For the full year 2023, Amgen now expects total revenues in the range of $26.6 billion to $27.4 billion; on a GAAP basis, EPS in the range of $14.30 to $15.41; capital expenditures to be approximately $925 million and share repurchases not to exceed $500 million.

The main issue for Amgen remains the takeover of Horizon Therapeutics. The Federal Trade Commission is working to block the roughly $28 billion transaction. The agency says Amgen could use its weight to pressure insurance companies and pharmacy benefit managers into favoring Horizon's two biggest products,

thyroid eye disease treatment Tepezza and gout treatment Krystexxa. According to Amgen Chief Executive Robert Bradway still expects the deal to close, as expected, in December. "We look forward to making our case in court in September and I am confident, rather, that we will prevail."

AbbVie improves its earnings outlook

AbbVie raised its earnings outlook, while its quarterly revenues totaled $13.8 billion, marking a decrease of 4.9% on a reported basis. By segment, AbbVie saw revenue declines in its immunology portfolio, down 5.5% ($6.81 billion), its hematologic oncology portfolio, down 10.4% ($1.47 billion), as well as a 13.9% drop in eye care. However, its aesthetics business inched up 1% while its neuroscience division jumped 13.6% ($1.47 billion.)

In the first half of 2023, AbbVie sales stood at $26 billion (-7,2%). The company is dealing with falling sales of Humira in immunology. On a six-month basis, sales of Humira decreased -25,2% to $7.55 billion, amid the rise of more affordable biosimilar competitors. Amgen has launched biosimilar Amjevita at a deep discount to Humira. According to AbbVie, its newer immunology drugs Rinvoq and Skyrizi are expected to drive growth. During the first half of 2023, their combined sales stood at $4.8 billion, up 49%.

In light of this effort, the pharma giant raised its 2023 adjusted EPS guidance range to $10.90 to $11.10, up from its previous prediction of $10.57 to $10.97.

BMS lowers its financial guidance

During the second quarter of 2023 and the first half of the year, BMS suffered from decline in sales and revenues, mainly due to lower sales of Revlimid ($1.46 billion, -41%), a medicine used for the treatment of certain cancers and serious conditions affecting blood cells and bone marrow. BMS' quarterly revenues slipped 6% to $11.2 billion. U.S. revenues decreased 5% to $7.9 billion in the quarter primarily due to lower sales of Revlimid resulting from generic erosion and an increase in the number of patients receiving free drug product for Revlimid, and to a lesser extent Pomalyst. While its in-line products portfolio experienced some revenue declines, including a category-wide slip from $8.7 billion to $8.6 billion, BMS' new products experienced 79% year-over-year growth.

During the first half of 2023, Bristol Myers Squibb posted revenues of $22.6 billion, a decline of 4%, primarily due to lower revenue for Revlimid ($3.2 billion, -39%). U.S. revenues remained consistent at $15.9 billion in the first half.

Bristol Myers Squibb revised its 2023 guidance, lowering its adjusting outlook for total revenues as well as EPS primarily due to "lower than expected sales of Revlimid, and to a lesser extent, Pomalyst. Revlimid revenues are now expected to be $5.5 billion, while the company noted that its EPS guidance reflects higher tax benefits resulting from a non-U.S. tax ruling.

GSK raises its full-year guidance

GSK raised its full-year profit and sales guidance after its second-quarter earnings beat expectations, helped by strong sales of its shingles vaccine Shingrix and HIV medicines. The drugmaker now expects adjusted earnings per share growth of 14-17% for the year, up from its earlier expectations of 12-15%; adjusted operating profit of 11-13% (versus 10-12%) and global turnover of 8-10% (versus 6-8%).

One year after the split with the consumer business, the market still waits for new product development to rebuild its portfolio. But the company announced better results than expected for the second quarter of 2023. Global sales stood at $9.16 billion, up 11% excluding Covid-19 solutions. Sales of Shingrix, the company's top-selling drug, generated $1.11 billion, beating analyst estimates of $1.10 billion. Sales of HIV treatments generated $2 billion, ahead of the market consensus of $1.9 billion.

The adverse impact of lower sales of Covid-19 solutions was one percentage point of growth in the quarter on Adjusted operating profit. GSK does not anticipate further significant Covid-19 pandemic-related sales or operating profit in 2023.

AstraZeneca reiterates its guidance

"Each of our non-COVID-19 therapy areas saw double-digit revenue growth, with eight medicines delivering more than $1bn of revenue in the first half, demonstrating the strength of our business", AstraZeneca CEO, Pascal Soriot said, announcing the company's results.

During the first half of 2023, total revenue stood at $22.3 billion, up 4% despite a decline of $2.18 billion from Covid-19 medicines. Excluding Covid-19 medicines, total revenues increased 16% and product sales, 15%. Core EPS increased 21% to $4.07.

Astra Zeneca reiterated its guidance for 2023. Total revenue from Covid-19 medicines (Vaxzevria17 and Covid-19 mAbs18) is expected to decline significantly in full-year 2023. During the first half of 2023, sales of these two products declined more than 85% to $155 million. ■

Synerlab Group

Welcome to our New World of Agility

We are a leading Multispecialist European CDMO, Trusted Solutions Maker

Offering superior quality at a competitive cost in a shorter timeline

Our mission is to support pharmaceuticals firms in

- R&D custom projects (development, product updates, clinical phase production sterile and non-sterile)
- Regulatory Affairs Services & Sale of Portfolio dossiers
- Contract Manufacturing (Oral Forms, Sterile multidoses, Lyophilized Product Sterile Injectables and API)

Our customers recognize our flexibility, proactive spirit, and fast decision-making, which gives us a strong agility that distinguishes us from our competitors

Synerlab GROUP

www.synerlab.com

Author

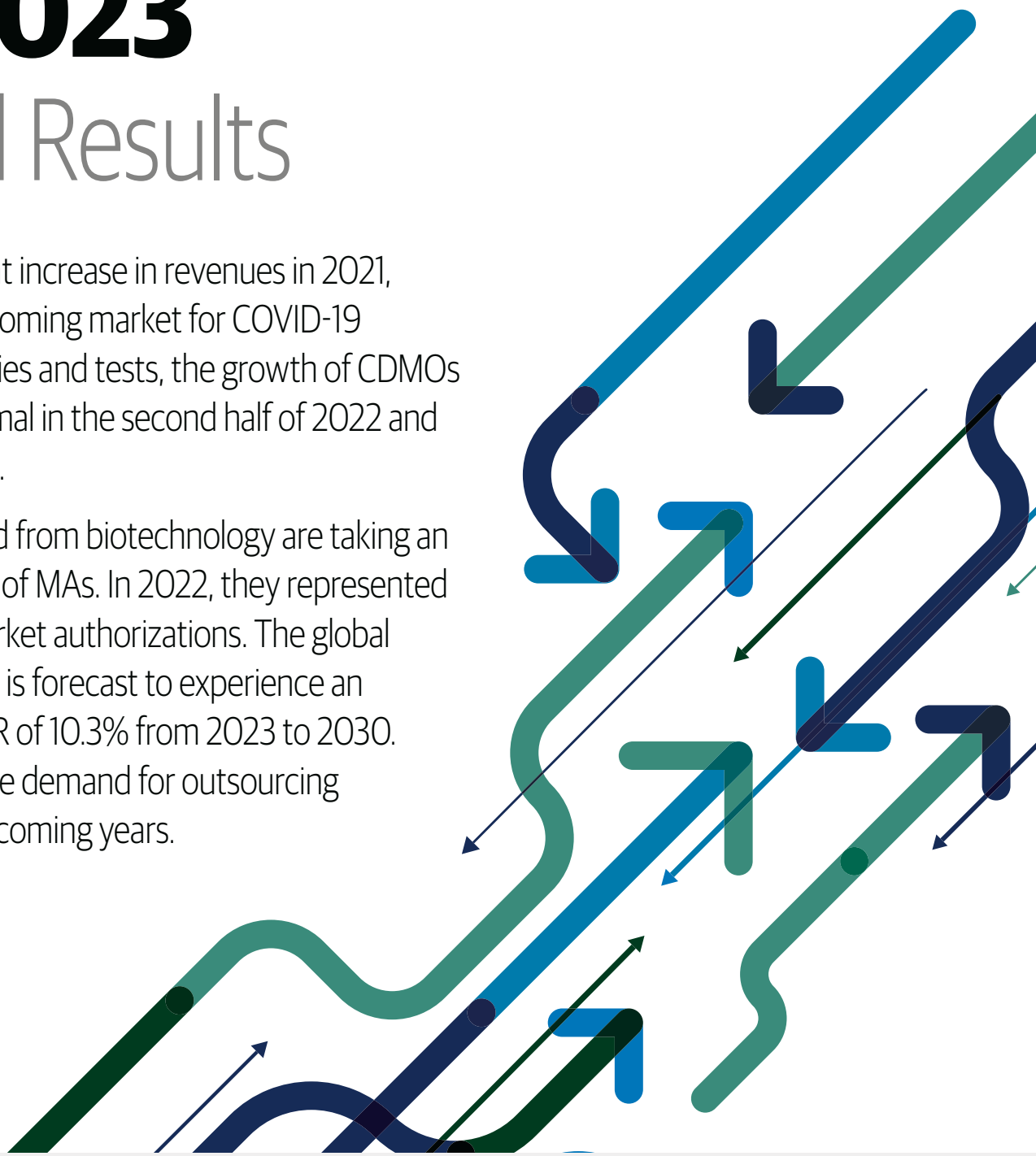
Jean-Louis Briau-Geneste

CDMOs: Financial performance H1 2023

Mixed Results

After a significant increase in revenues in 2021, driven by the booming market for COVID-19 vaccines, therapies and tests, the growth of CDMOs returned to normal in the second half of 2022 and first half of 2023.

Products derived from biotechnology are taking an increasing share of MAs. In 2022, they represented 50% of FDA market authorizations. The global biologics market is forecast to experience an impressive CAGR of 10.3% from 2023 to 2030. This creates huge demand for outsourcing capacity for the coming years.



Biotechnology: new sources of growth

In 2022, 960 next-generation biotherapeutics were in development from Phase I through filing with a regulatory agency. This next-generation biotherapeutic pipeline has grown significantly in recent years, with a 20% CAGR since 2017 according to IQVIA. Cell therapies represent the largest share, with 40% of these being investigated for a range of cancers, predominantly non-rare solid tumor malignancies

Currently, more than 2,700 companies and more than 100 academic or research groups around the world are involved in the R&D pipeline. While emerging biopharma companies (EBP) were responsible for only one-third of innovation in 2002, they now are responsible for two-thirds of the R&D pipeline, highlighting the increasing importance of innovation from these smaller companies. Emerging biopharma company R&D activity is spread out across major geographies, with more than 4,500 products under development by emerging biopharma companies

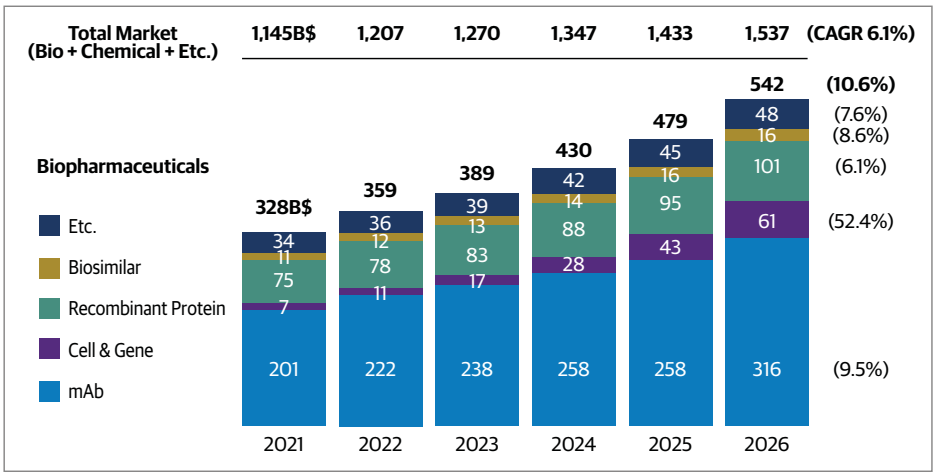
The global biologics market is forecast to experience an impressive CAGR of 10.3% from 2023 to 2030.

The number of novel active substances (NASs) originated by EBP companies that have launched has doubled in the last five years. 26 NASs launched in 2022 that originated from an EBP company.

Over the past 15 years, products derived from biotechnology have taken an increasing share of MAs. In 2022, they represented 50% of FDA market authorizations.

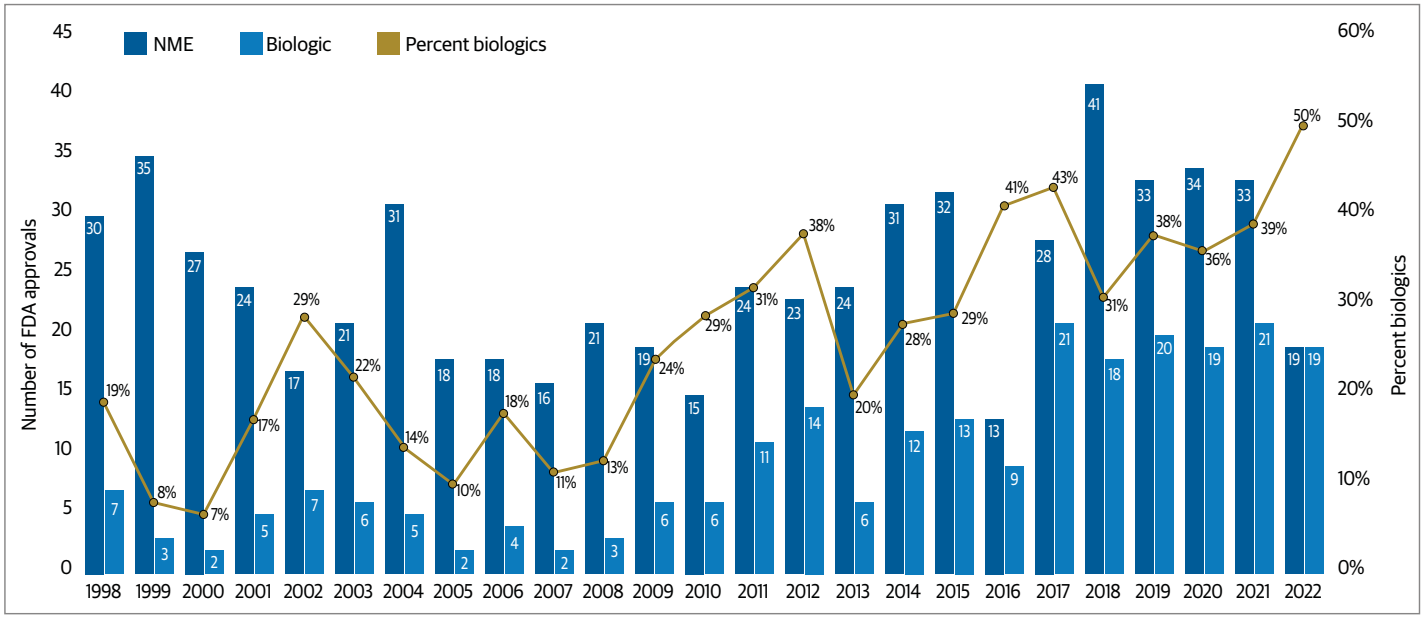
With a fully mature cell and gene therapy pipeline, the FDA approved 26 new biotechnology molecules in the first half of 2023, i.e. two-thirds of the 35 new MAs.

BIOPHARMACEUTICAL MARKET SIZE



Source: EvaluatePharma

FDA APPROVALS: SHARE OF BIOTECHNOLOGY-DERIVED PRODUCTS



Source: Evaluate Pharma

The CDMO value chain is becoming broader

The growing demand for organic products creates huge needs for outsourcing capacity. Pharmaceutical and biotech companies have limited manufacturing capabilities, and are turning to specialized biologics outsourcing service providers with deep expertise and experience. This strategic approach not only helps reduce costs, but also improves overall operational efficiency. The biologics outsourcing market is expected to witness double-digit growth in coming years.

The global bio-CDMO market is valued at US$15.7 billion in 2023 and is forecast to reach US$20.3 billion by 2026, at an average growth rate of 8.9% for the next five years

Leveraging their vast expertise and solid experience spanning the entire lifecycle of biologics development, major bio CDMOs (BioXcellence, Lonza, Samsung, Wuxi, etc.) have strategically deployed new expertise to establish integrated platforms that provide comprehensive end-to-end CRDMO services for ADC and vaccine discovery, development and manufacturing.

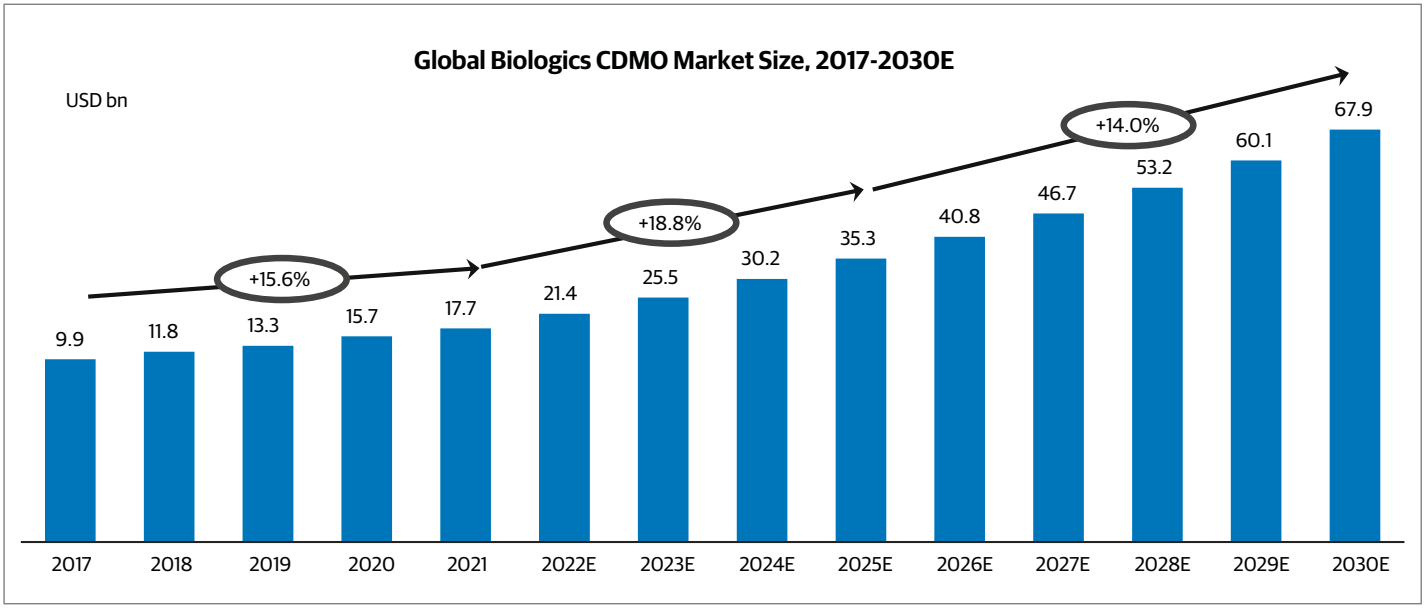
Biotech funding has declined steeply

However, EBPs face a radically different financing environment than two years ago, when many were adopted by public markets and venture capital firms. Biotechnology companies with large drug pipelines now have limited budgets to develop the products in those pipelines.

After highly productive financing for the industry in 2020 and 2021 (raising nearly US$240 billion in two years), 2022 saw a 54% annual decline in the levels of capital available to the biotech sector in the US and Europe. The US$54.6 billion raised in 2022 represented the lowest annual investment in the industry since 2016, but this figure is broadly in line with pre-pandemic expectations (indeed, if 2020 and 2021 are omitted, total financing for 2022 is similar to the industry's annual financing average over the previous decade). However, the two years of exceptionally high financing during the pandemic have created unusual conditions within the biotech sector, and companies must now adjust to the removal of those conditions according to Ernst & Young.

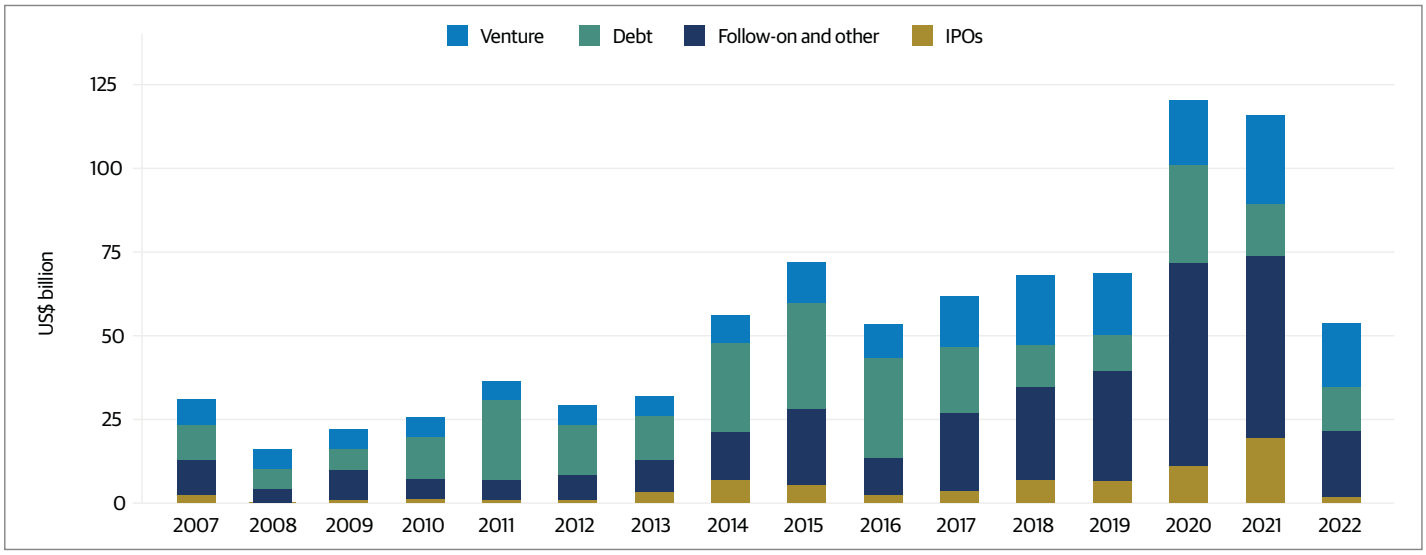
As such, biotechnology fundamentals should weather the current financial storm, and the continued growth of the sector.

GLOBAL BIOLOGICS CDMO INDUSTRY CONTINUES TO GROW



Source: Frost & Sullivan, September 2022

FIGURE 4: CAPITAL RAISED IN THE US AND EUROPE, 2007-22



Source: EY analysis, Capital IQ and Dow Jones VentureSource.

Growth of the biosimilar market

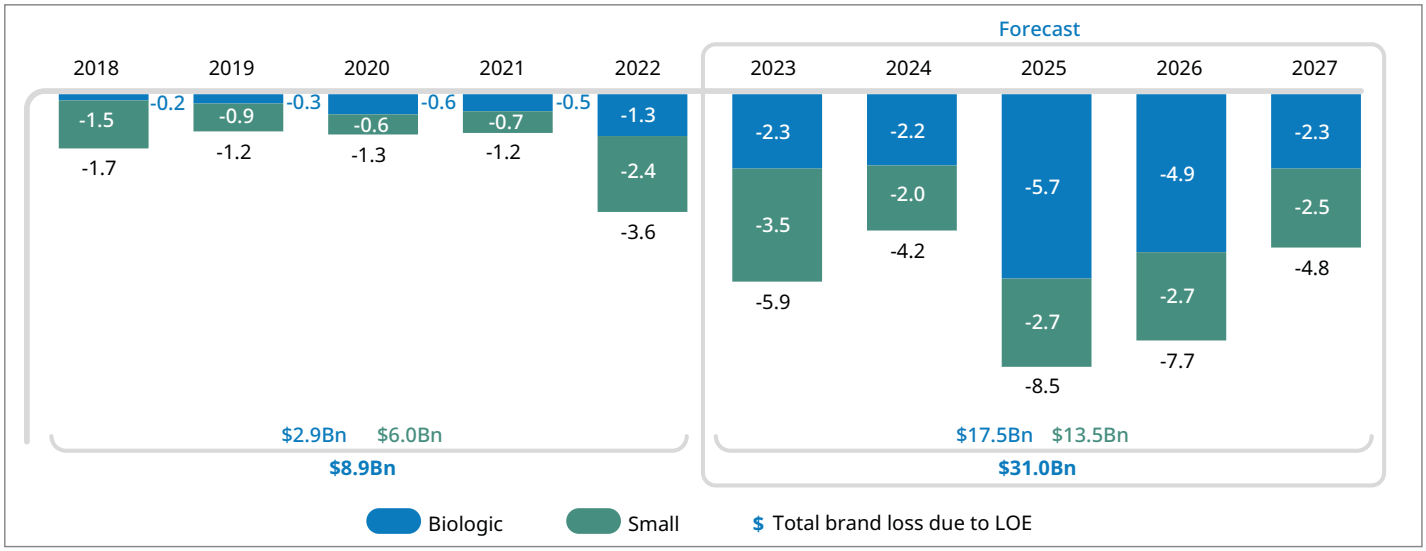
The global biosimilar industry has become a favorable market environment for development, reflecting the continued expiration of patents for original drugs.

The impact of losses of patent exclusivity (LOE) in the big five European markets (Germany, France, Italy, Spain and the United Kingdom) is expected to more than triple over the next five years. The impact of exclusivity losses will reach $31Bn over 5 years, with more than half due to the availability of biosimilars according to IQVIA.

The European biosimilar market is the largest in the world, with the first product having been launched in 2006. The biologics molecules facing biosimilar competition increased from 2013 to 2018 in the European Union, with the number of EMA approvals increasing in 2017 and 2018.

Growth in the biosimilar industry is set to continue, as more than 15 biopharmaceutical patents expire by 2032. According to EvaluatePharma, a market research firm, the biosimilar market is expected to grow at an average annual growth rate of 7% from $11.1 billion in 2021 to $18.1 billion in 2028.

FIGURE 5: EU4+UK IMPACT OF BRAND LOSSES OF EXCLUSIVITY 2018-2027, US$BN



Source: IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.

Ongoing global macroeconomic uncertainties

Outsourcing activities is a way for many pharmaceutical companies to improve operational efficiency, expand geographic presence, reduce resource costs, gain therapeutic expertise and improve on-demand services

CDMOs played an important role in increasing vaccine production during the COVID-19 pandemic, and outside of COVID-19, Big Pharma has used CDMOs to unlock manufacturing investments and help finance pipelines or business priorities.

In 2022 and again in the first half of 2023, the effects of COVID on drug development and manufacturing supply chains are still being felt. Shortages of certain materials persist, with increasingly long supply times. Industries supplying consumables for production lines are lacking capacity for some of them.

With the Covid crisis, Europeans and Americans have become aware of the considerable volumes of materials and products from China and India that are infiltrating Western markets. Drug stock-outs have become a major concern in drug supply chains and government administrations are becoming aware of these new issues. In order to sustain local production, several European countries are proposing a policy of increasing the prices of mature products.

Globally, CDMOs face inflation in the form of rising costs of materials, services and wages; increasingly high interest rates; unstable tax policies and increasingly cautious investors in this period of economic crisis

In this uncertain economic context, the financial results during the first half of 2023 reveal a slowdown in turnover for certain bioCDMOs which had benefited from the large quantities of vaccine production.

However, the major European and Asian BioCDMOs are showing good organic growth and are largely offsetting the decline in production of Covid vaccines. The most dynamic have implemented "Follow and Win the Molecule" strategies, regularly bringing new projects into the pipeline with accelerated phase III projects and commercial biological product projects.

CDMOS MARKET CAPITALIZATION

Company	Share Price 31 June 2022	Share Price 31 June 2023	Share Price chg %	Share price 25 August 2023	Share Price chg %	Market capitalisation 28 August 2023
Catalent ($)	107.29	37	-65.5	44.89	21.3	8,092B
Emergent bioSolutions Inc ($)	31.25	7.35	-76.5	4.54	-38.2	235,20M
Avid BioServices ($)	15.17	13.97	-7.9	12.04	-13.8	755,26M
Societal CDMO ($)	0.76	1.1	44.7	0.405	-63.2	36.59M
West Pharmaceutical Services ($)	302.37	382.47	26.5	393.73	2.9	29.08B
Europe						
Lonza Group (CHF)	509	533.4	4.8	473.3	-11.3	34.99B
Siegfried (CHF)	610.3	737	20.8	783	6.2	3.33B
Oxford Biomedica (£)	460	420	-8.7	323	-23.1	312.45M
Lab Farmaceuticos ROVI (EUR)	59.6	42.34	-29.0	50.25	18.7	2.835M
Asia						
Samsung Biologics (KRW)	790	744	-5.8	757	1.7	50086B
Wuxi Biologics (HKD)	71.8	37.55	-47.7	45.95	22.4	24026.5M

Source: PHARMAnetwork studies

Catalent flags problems at its manufacturing plants and cuts forecast

As of May 2023, Catalent had delayed the release of its quarterly results three times in less than a month, following production issues at three of its key facilities, including in Brussels, where it carries out filling work for Wegovy, Novo Nordisk's anti-obesity drug. In June, the company told investors it needed "a little more time" to resolve problems at the Brussels factory. The FDA website states that there will be "limited availability through September 2023" of Wegovy's three formulations.

In May, Catalent announced that its revenue in the quarter ended March 31 had fallen by 19%, and the company cut its annual revenue forecast for the second time.

Catalent also delayed its cost-cutting plans following costly corrective actions to address quality control deficiencies identified during multiple FDA inspections at three factories.

For Q3 2023, Catalent published net revenue of $1.04 billion, down 19% as reported or 17% in constant currency from the $1.27 billion reported for the same period a year ago. Overall, organic net revenue (i.e., excluding the effect of acquisitions, divestitures, and currency translation) decreased by 19% over the period.

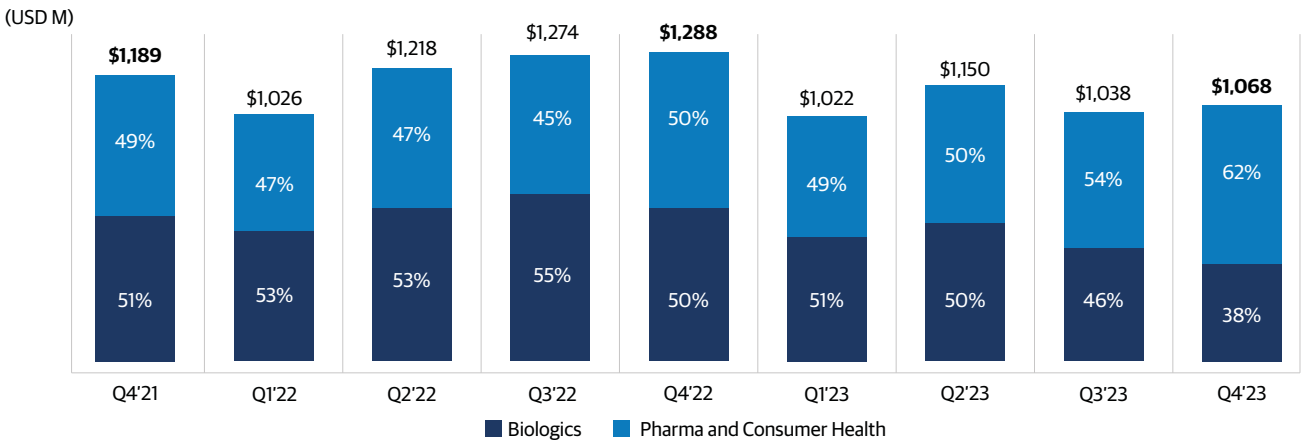
EBITDA from operations was a loss of $125 million, down $433 million from the $308 million profit reported in the third quarter a year ago. Third quarter fiscal 2023 adjusted EBITDA was $105 million, or 10% of net revenue, compared to $339 million, or 27% of net revenue, in the third quarter a year ago. This represents a decrease of 69% as reported and a decrease of 68% on a constant-currency basis, compared to fiscal 2022.

As of March 31, 2023, Catalent had $4.85 billion in total debt, and $4.60 billion in total debt net of cash, cash equivalents, and marketable securities, compared to $4.38 billion in total net debt as of December 31, 2022.

From its highest level at $140 in 2021, Catalent's stock fell sharply at the end of October 2022 and was listed in the first week of November 2022 at $41. The stock then fell on May 15, 2023 to $32 following successive postponements of the communication of third quarter results and after reducing its annual revenue forecast for the second time.

In July, Catalent appointed Matti Masanovich Senior Vice President and Chief Financial Officer. Mr. Masanovich will have responsibility for all

CATALENT QUARTERLY NET REVENUE BY SEGMENT[1]



(USD M)	Q4'21	Q1'22	Q2'22	Q3'22	Q4'22	Q1'23	Q2'23	Q3'23	Q4'23
Biologics	$ 606	$ 548	$ 641	$ 700	$ 645	$ 523	$ 580	$ 475	$ 406
Pharma and Consumer Health	583	478	577	574	643	499	570	563	662
Subtotal	**$ 1,189**	**$ 1,026**	**$ 1,218**	**$ 1,274**	**$ 1,288**	**$ 1,022**	**$ 1,150**	**$ 1,038**	**$ 1,068**
Inter-Segment Revenue Elimination									
Net Revenue	**$ 1,189**	**$ 1,026**	**$ 1,218**	**$ 1,274**	**$ 1,288**	**$ 1,022**	**$ 1,150**	**$ 1,038**	**$ 1,068**

Source: Catalent
Note: Segment information for periods ending on or before June 30, 2022 have been restated to align with our new & current reporting structure. Please see our earnings release, dated November 1, 2022, for further information.
[1]Data reflect corrections to FY'22 results.

aspects of Catalent's global financial operations, including financial planning and analysis, controllership, public reporting and investor relations, capital markets activities, bill payment and collection, tax, and treasury. He will also be a member of Catalent's executive leadership team, the highest level of company management.

At the end of August, Catalent published the results for its fourth quarter ending June 30. Net revenue of $1.07 billion decreased 17% as reported, or 17% in constant currency, from the $1.29 billion reported for Q4 a year ago. Overall organic net revenue (i.e., excluding the effect of acquisitions, divestitures, and currency translation) decreased by 19% over the same period.

Net loss and loss per basic and diluted share were $86 million and $0.48 respectively, compared to net earnings attributable to common shareholders of $168 million, or $0.94 per basic share and $0.93 per diluted share in the fourth quarter a year ago.

EBITDA from operations was $18 million, a decrease of $299 million from $317 million in the fourth quarter a year ago. Fourth quarter fiscal 2023 adjusted EBITDA was $139 million or 13% of net revenue, compared to $358 million or 28% of net revenue, in the fourth quarter a year ago. This represents a decrease of 61% as reported and on a constant-currency basis, compared to the fiscal 2022 fourth quarter.

Catalent - Fiscal Year 2023 Financial Summary

Catalent Fiscal 2023 net revenue of $4.28 billion decreased by 11% as reported or 9% in constant currency, compared to fiscal 2022. Organic, constant-currency net revenue decreased 11% compared to FY'22. Fiscal 2023 adjusted EBITDA of $714 million was down 43% as reported or 42% in constant currency, compared to FY'22.

Catalent facing pressure from Elliott and has other activists in its stock

When reporting its fourth-quarter results on August 29, Catalent stated that it had added four new directors to its board and would conduct a strategic review, after reaching a deal with activist investor Elliott Investment Management. The company has been the subject of interest for months from private equity firms and strategic buyers.

Emergent Biosolutions Inc 2023 CDMO services revenue down

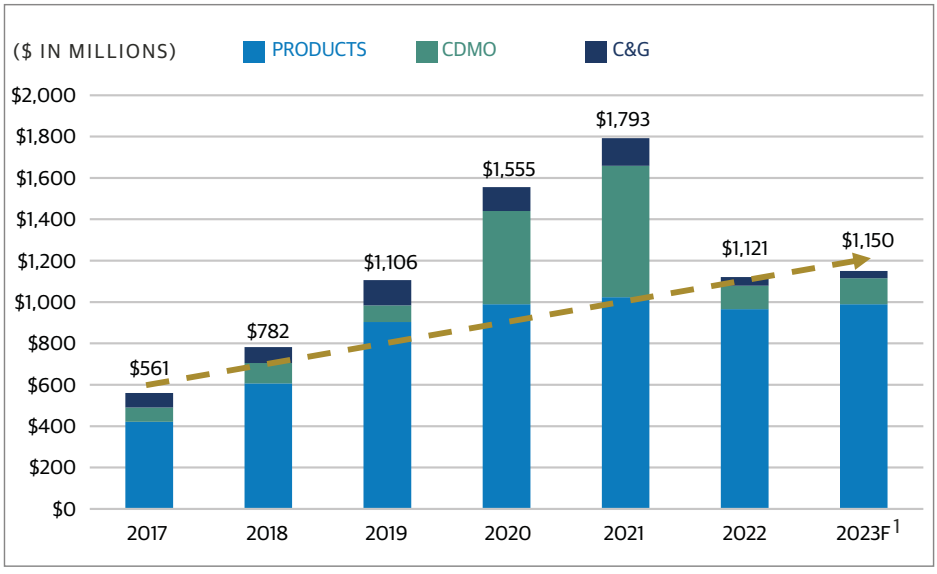
Emergent Biosolutions Inc provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics developed and manufactured for governments and consumers. In July, EBS announced that it had been awarded a 10-year contract by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), valued at up to a maximum of $704 million, for advanced development, manufacturing scale-up, and procurement of Ebanga™ (ansuvimab-zykl), a licensed treatment for Ebola virus disease (EVD).

Emergent Biosolutions also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers.

For Q1 2023, revenues from contract development and manufacturing services decreased $38.4 million as compared with Q1 2022. The decrease was primarily due to $19.2 million less revenue related to reduced production activities at the company's Bayview facility, as a result of a halt in manufacturing under the Janssen contract in 2022. Additionally, the decrease also reflects reduced production at the company's Camden facility. The decreases were slightly offset by an increase in production at the company's Canton facility.

For Q1 2023, revenues from contract development and manufacturing leases decreased $7.2 million as

EMERGENT BIOSOLUTIONS HISTORICAL REVENUES - 2017-2023F



Source: Emergent Biosolutions
1. Reflects the midpoints of the ranges for each category indicated in a press release issued by the Company on May 9, 2023.

EMERGENT BIOSOLUTIONS CDMO SERVICES REVENUE - SINCE 2014 LAUNCH

	Launch and Initial Ramp Up						COVID Response		Business Re-baselining	
[$M]	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023 Forecast
CDMO Revenues	**$30.9**	**$43.0**	**$49.1**	**$68.9**	**$98.9**	**$80.0**	**$450.5**	**$634.6**	**$113.3**	**$100.0[1]**
Total Period Revenues	$404.5	$489.3	$488.8	$560.9	$782.4	$1,106.0	$1,555.4	$1,792.7	$1,120.9	$1,150.0[2]
CDMO as % of Total Revenues	8%	9%	10%	12%	13%	7%	29%	35%	10%	11%

Source: Emergent Biosolutions
1. Reflects the midpoint of the range for CDMO revenues as indicated in the press release issued by the Company on May 9, 2023.
2. Reflects the midpoint of the range for Total revenues as indicated in the press release issued by the Company on May 9, 2023.

compared with Q1 2022. The decrease was primarily due to a reduction in lease revenues related to the Janssen contract termination.

For Q2 2023, revenues from contract development and manufacturing services increased by $23.7 million as compared with Q2 2022. This was primarily driven by work at the Company's Canton facility for a CDMO customer and resolution of a customer's outstanding obligation. In the prior year quarter, there was a reversal of revenue related to the halt in manufacturing under the Janssen Agreement.

CDMO leases for Q2 2023, revenues from contract development and manufacturing leases increased by $7.2 million as compared with Q2 2022. The lease revenue in the current year quarter is related to the Company's Canton facility. In the prior year quarter, there was a reversal of revenue recognized related to the Janssen Agreement termination.

Avid Bioservices: strong backlog and a mature pipeline

"Fiscal 2023 was a record-setting year, with Avid recording its highest single quarter revenue, its highest annual revenue, and ending the year with its largest backlog to-date," stated Nick Green, president and CEO.

Revenues for the fourth quarter of fiscal 2023 were $39.8 million, representing a 28% increase compared to $31.2 million recorded in the prior year period. For the 2023 full fiscal year, revenues were $149.3 million, a 25% increase compared to $119.6 million in the prior year period. For both the quarter and the fiscal year, the increase in revenues can primarily be attributed to increases in manufacturing runs and process development services provided to new customers.

As of April 30, 2023, the company's revenue backlog was $191 million, representing an increase of 25% compared to $153 million at the end of the fourth quarter of fiscal 2022. The company expects a growing portion of the backlog will extend beyond a year.

Gross margin for the fourth quarter of fiscal 2023 was 21%, and in-line with a gross margin of 22% for the fourth quarter of fiscal 2022. Gross margin for the 2023 full fiscal year was 21%, compared to a gross margin of 31% for the same period during fiscal 2022.

For the fourth quarter of fiscal 2023, the company posted a net loss of approximately $0.3 million or $0.00 per basic and diluted share, as compared to net income of $115.6 million or $1.87 per basic and $1.65 per diluted share, for the fourth quarter of fiscal 2022. For the 2023 full fiscal year, the company recorded net income of approximately $0.6 million or $0.01 per basic and diluted share, as compared to net income of $127.7 million or $2.08 per basic and $1.84 per diluted share, respectively, during the same prior year period.

The company's commercial team signed multiple new orders during the fourth quarter, totaling approximately $55 million net. These orders are with new and existing customers, and span all areas of the business, from process development to commercial manufacturing.

During fiscal 2023, the company completed and opened each of its mammalian expansion projects in the same quarter, as backlog equaled or exceeded prior capacity. As a result, the company transitioned to a fully disposable platform with more than 20,000 liters of state-of-the-art capacity. The company's remaining expansion project is the build-out of its new CGT Facility, which will support early-stage development through commercial manufacturing.

The company has already launched analytical and process development capabilities at this facility and remains on track to launch the CGMP manufacturing suites by the end of the third quarter of calendar 2023.

Avid Bioservices is expanding its fiscal 2024 revenue forecast to between $145 million and $165 million.

Societal CDMO: significant progress on senior debt reduction

Revenues for the quarter ended June 30, 2023 were $21.8 million, compared to $23.2 million for the comparable 2022 period. The decrease of $1.4 million was primarily driven by a decrease in revenue from the company's largest commercial customer, Teva, due to a scheduled shutdown of the company's packaging line to implement the upgrades required to comply with new serialization aggregation compliance standards.

Interest expense was $2.3 million for the three months ended June 30, 2023, down on the $3.4 million for the comparable period of 2022. The decrease of $1.1 million was primarily due to a significantly reduced amount of aggregate principal and lower interest rates under the company's refinanced debt as compared to the borrowings outstanding during the period ended June 30, 2022.

For the quarter ended June 30, 2023, the company posted a net loss of $3.2 million or $0.04 per diluted share, as compared to a net loss of $3.1 million or $0.06 per diluted share, for the comparable period of 2022. EBITDA, as adjusted* for the period was $2.8 million compared to $4.0 million in the prior year period. The $1.2 million decrease in EBITDA is primarily due to lower revenue during the period.

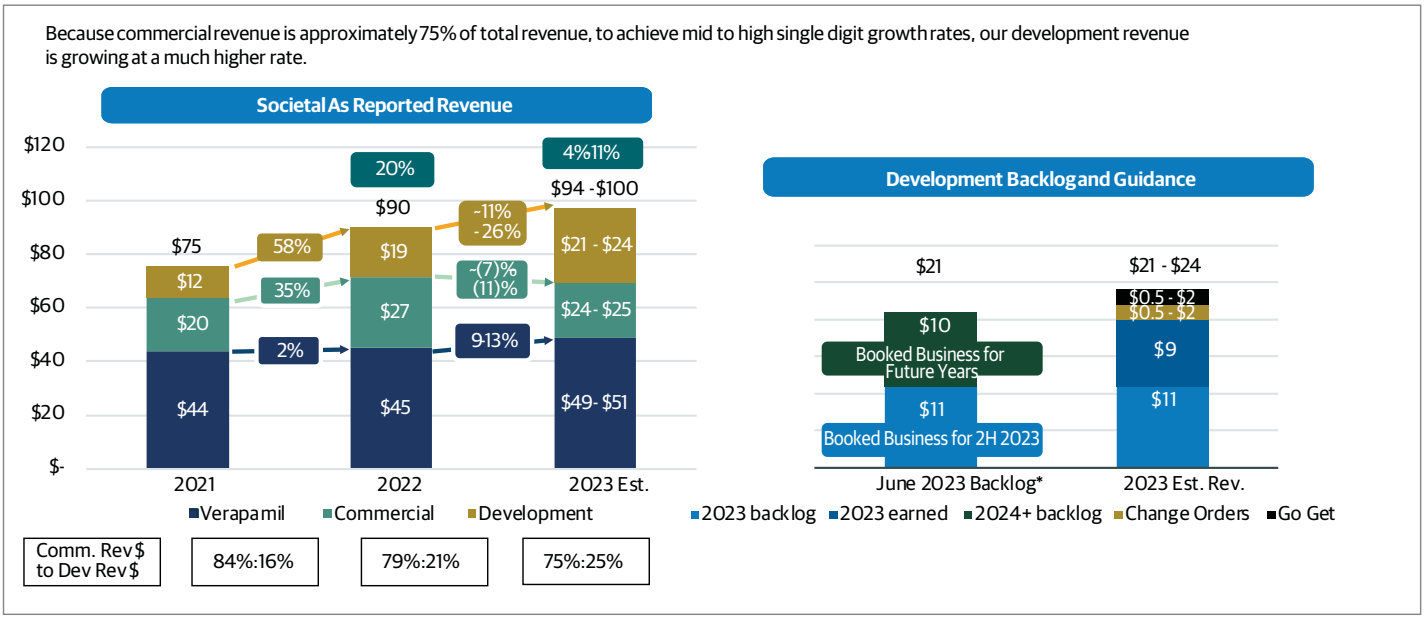
Financial results for the six months ended June 30, 2023

Revenue for the six months ended June 30, 2023 was $43.3 million, compared to $44.3 million for 2022. The decrease of $1.0 million in revenue was primarily driven by the decreases in revenues from Teva and InfectoPharm, which were partially offset by an increase in pre-commercial development revenues, as described above.

Interest expense was $4.4 million and $6.8 million for the first six months of 2023 and 2022, respectively. The decrease of $2.4 million was primarily due to a significantly reduced amount of aggregate principal and lower interest rates under the company's refinanced debt as compared to the borrowings outstanding during the period ended June 30, 2022.

For the six months ended June 30, 2023, Societal reported a net loss of $7.9 million, or $0.09 per diluted share, compared to a net loss of $7.4 million, or $0.13 per diluted share, for 2022. EBITDA as adjusted for the first six months was $3.4 million compared to $6.8 million in the prior year period. The $3.4 million decrease in EBITDA is primarily due to mix of revenue and related fixed cost absorption offset by reduced selling, general and administrative costs.

SOCIETAL CDMO - REVENUE TREND BY TYPE



Source: Societal CDMO

For illustrative purposes only, revenue mix, timing, estimates, assumptions, backlog, attrition, win-rate and the actual growth of revenue may vary significantly, and we may not be able to achieve our financial goals or anticipated revenue mix. The information provided is illustrative only, the growth cycle may not be achieved and there is continued uncertainty relating to any guidance contained herein. There can be no assurance that such results will occur or that such results may be materially different from actual results.

Interest expense was $4.4 million and $6.8 million for the first six months of 2023 and 2022, respectively. The decrease of $2.4 million was primarily due to a significantly reduced amount of aggregate principal and lower interest rates under the company's refinanced debt as compared to the borrowings outstanding during the period ended June 30, 2022.

Societal CDMO has the following targets for fiscal 2023:

• Revenue: $94 to $100 million, an increase of 4% - 11% over 2022

• Net loss: $(10.7) to $(7.7) million

“However, the period was not without challenges, as our customers continue to face an unfavorable financing environment. While we do not believe that our topline year-end revenue guidance will be impacted by these market factors, we do believe that our EBITDA guidance requires revision. We had previously guided to a 2023 full year EBITDA of between $15 and $18 million. Today we are revising this guidance to between $12 and $15 million” said David Enloe, chief executive officer of Societal.

West Pharma: “a solid first-half to 2023”

"We had a solid first-half to 2023, and with the momentum of our high-value product capacity expansion projects, we are well positioned for an even better second-half of the year," said Eric M. Green, President, Chief Executive Officer and Chair of the Board. "While COVID-19 related sales continued to decline as expected, our base Proprietary Products business again grew organically by double digits. We see continued stability in both near- and long-term demand trends for our HVP components, devices and systems, and our team members remain focused on creating value-added solutions for our customers."

Q2 2023 Proprietary products segment: Net sales declined by 5.5% to $618.0 million. Organic net sales (excluding changes in currency translation and impact of a recent divestiture) also declined by 5.5%. This was primarily driven by an expected reduction in COVID-19 related sales. High-value products (components and devices) represented more than 70% of segment sales in the period led by customer demand for Westar® components and HVP devices. The Generics market unit had high-single-digit organic net sales growth, and the Pharma market unit had mid-single-digit organic net sales growth. The Biologics market unit had a double-digit decline in organic net sales,

due to a decline in COVID-19 related demand. Excluding this COVID-19 impact, the Proprietary Products segment, as well as the Biologics and Generics market units, would have had double-digit organic net sales growth.

Contract-manufactured products segment: Net sales grew by 15.3% to $135.8 million. Organic net sales grew by 14.3% with currency translation increasing sales growth by 100 basis points. Segment performance was led by growth in sales of components associated with injection-related devices.

Full-year 2023 updated financial guidance:

- The Company is updating full-year 2023 net sales guidance to a new range of $2.970 billion to $2.995 billion, compared to a prior range of $2.965 billion to $2.990 billion.
- The company are committing $350 million of CAPEX in 2023 to further expand capacity to prepare for existing base demand and potential future drug launches

Lonza delivers 5.6% CER sales growth In H1 2023

"As we look towards H2, ramp-up of new commercial assets in Biologics will support sales growth. More widely, we will also continue to focus on delivering our growth projects and driving continuous improvement across our global network," said Pierre-Alain Ruffieux, CEO, Lonza.

In H1 2023, Lonza delivered CHF 3.1 billion sales and 5.6% CER sales growth, corresponding to around 10% CER underlying sales growth and CHF 922 million CORE EBITDA resulted in a margin of 30%

Business highlights in the first half included the acquisition of Synaffix and its leading clinical-stage technology platform focusing on linker technology for antibody-drug conjugates (ADCs). Lonza also entered an agreement with Vertex to build a dedicated manufacturing facility for type 1 diabetes cell therapies at its Portsmouth (US) site.

Lonza updated its guidance to reflect current market dynamics impacting demand for early-stage services and nutraceutical capsules driving underutilization. Outlook 2023 was updated from high-single-digit to mid-to-high-single-digit CER sales growth, and from 30-31% to 28-29% CORE EBITDA margin. Mid-term sales guidance was confirmed, with a margin range updated from 33-35% to 31-33%.

This is surely one of the best margins in the CDMO industry in Europe.

Divisional overview

The Biologics Division reported sales growth of 1.9%. Strong performance in Bioconjugates, Mammalian and Microbial fully offset the loss of mRNA sales and the Allakos cancellation fee in H1 2022. The division delivered a CORE EBITDA margin of 31.5%.

Small Molecules reported sales growth of 37.5% and a CORE EBITDA margin of 34.9% driven by high asset utilization, favorable mix, and the division's ongoing focus on higher value and more complex offerings. This strong performance built on a low base in H1 2022.

Cell & Gene reported 10.8% sales growth, and a CORE EBITDA margin of 19.6%. This was driven by strong momentum in Bioscience and the positive impact of the Codiak BioSciences termination following its bankruptcy filing. Weaker performance in Cell & Gene Technologies was due to the impact of lower early-stage biotech funding and some customer clinical-stage failures.

Capsules & Health Ingredients reported flat sales of 0.3% and a CORE EBITDA margin of 31.9%. Sales growth in pharma hard capsules was offset by lower demand for nutraceutical capsules. Margin was impacted by underutilization and higher raw materials costs, which were only partially offset by pricing adjustments and cost savings.

LONZA - FINANCIAL RESULTS BY DIVISION H1 2023

	Sales Growth CER[1]	CORE EBITDA margin	Margin change AER[2]
Biologics	1.9%	31.5%	(5.8)ppts
Small Molecules	37.5%	34.9%	5.0ppts
Cell & Gene	10.8%	19.6%	(2.7)ppts
Capsules & Health Ingedients	0.3%	31.9%	(3.3)ppts
Lonza	**5.6%**	**30.0%**	**(3.1)ppts**

Source: Lonza

CHF 765 million CAPEX executed in H1 2023

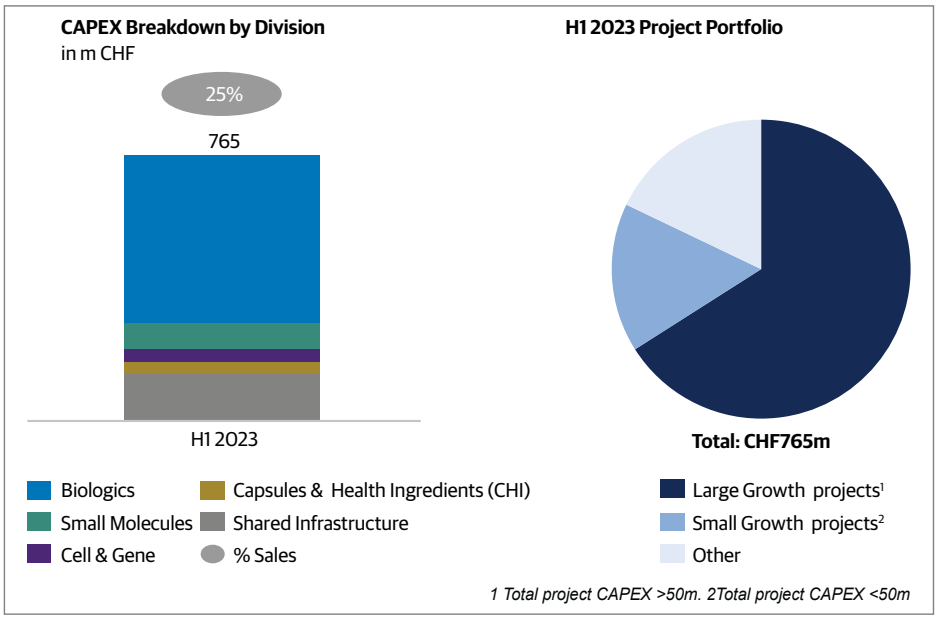
In Visp (CH), two new bioconjugates manufacturing suites came online, alongside a clinical and commercial drug product manufacturing line. Lonza also extended Biologics Early Development Services (EDS) into the US market, with the opening of a new laboratory in Cambridge (US).

In June Vertex Pharmaceuticals Incorporated and Lonza announced a strategic collaboration to support the manufacture of Vertex's portfolio of investigational stem cell-derived, fully-differentiated insulin-producing islet cell therapies for people with T1D, currently focusing on the VX-880 and VX-264 programs that are currently in clinical trials.

Under the terms of the collaboration, Vertex and Lonza will partner in the process development and scale-up for the manufacturing of the product portfolio, and co-invest to build a dedicated new facility in Portsmouth, New Hampshire (US). Operated by Lonza, the facility will span more than 130,000 square feet and is anticipated to create up to 300 new jobs at peak capacity. Construction is scheduled to begin later this year.

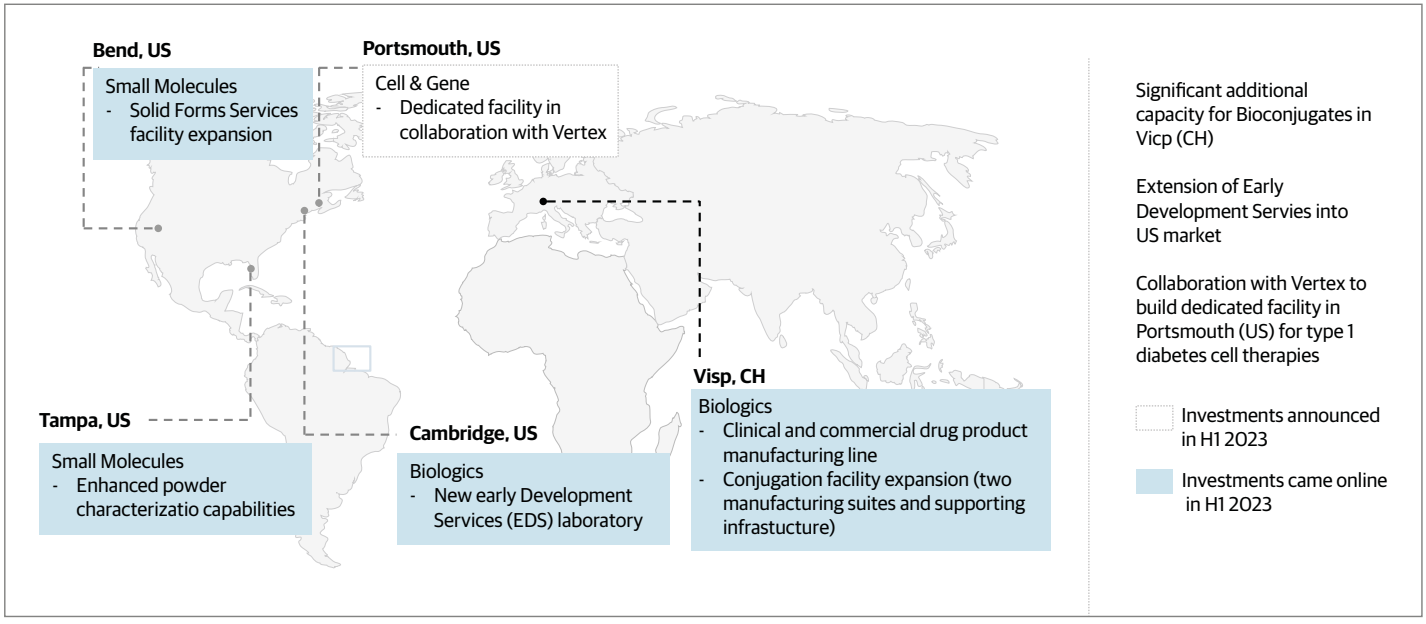
The dedicated facility will complement Lonza's global cell and gene technologies manufacturing network, which supports customers in developing, de-risking, commercializing

LONZA - CONTINUED PROGRESS ON GROWTH INVESTMENTS



Source: Lonza

LONZA - CONTINUED PROGRESS ON GROWTH INVESTMENTS



Source: Lonza

and scaling their emerging therapies. Lonza's scientific, regulatory and manufacturing expertise, its focus on operational excellence, and first-hand experience supporting the commercialization of marketed cell therapy products is expected to accelerate the development and commercialization of Vertex's potentially transformative therapies.

Siegfried posts continued growth in a challenging environment

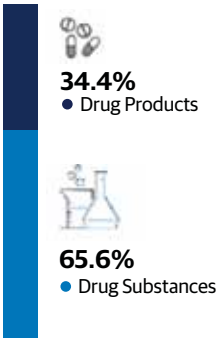
In the first half of the year, Siegfried's business model with its well-diversified portfolio of products and customers, plus its strong position as one of the globally leading CDMO, has once again proven its resilience to risks and volatility resulting from continuing macroeconomic and geopolitical uncertainties. The company was able to keep up its dynamic pace and overcompensate for the phasing out of sizeable vaccines business while keeping the Core EBITDA margin well above the 20% mark.

In the first half of 2023, Siegfried (SIX: SFZN) continued its growth trajectory and more than offset the phasing out of sizeable vaccines business since 2022. Significant progress has been made in the implementation of the EVOLVE corporate strategy which is geared towards long-term profitable growth in core areas and beyond.

Net sales amounted to CHF 607.1 million, an increase of 3.5 percent in Swiss Francs and 6.8 percent in local currencies. While the growth in the first half of 2023 was fueled by the Drug Substances business and its strong expansion of existing business, successful acquisition of new projects and an active portfolio management, the underlying business in Drug Products also developed well.

Core EBITDA amounted to CHF 125.7 million (prior period: CHF 130.2 million), representing a robust Core EBITDA margin of 20.7% (prior period: 22.2%). Core net profit amounted to CHF 58.9 million (prior period: CHF 65.2 million). Cash flow from operating activities increased to CHF 78.8 million (prior period: CHF 76.3 million).

SIEGFRIED - STRONG GROWTH DELIVERED



Change H1 2022 – H1 2023

CHF million	H1 2023	H1 2022	Change
Drug Substances	398.5	339.5	+17.4% (+20.2% in LC)
Drug Products	208.6	247.2	-15.6% (-11.7% in LC)
Total	607.1	586.7	+3.5% (+6.8% in LC)

- Net sales grew by 6.8% in Local Currencies (LC), strong FX headwind across all currencies
- 30% sales recorded in CHF, 58% in EUR, 11% in USD
- Strong development of underlying business

Source: Siegfried
Note: Net sales split H1 2022: 42.1% Drug Products, 57.9% Drug Substances

For Drug Products, the integration of the Spanish sites is now completed and they are already attracting new business. Their transformation into highly flexible CDMO platforms concluded with the opening of the new Center of Excellence in Barcelona in March 2023. The development center provides a wide range of development services with flexible pilot capacities, boosting Siegfried's global Drug Products network and its ability to acquire new business in that space.

Significant investments in the existing network

In Minden, Germany, Siegfried is investing up to CHF 100 million in building a new large-scale production plant for Drug Substances. The new production plant will not only significantly increase the capacity of Siegfried's Drug Substance business, but also expand the technological capabilities and the flexibility of Siegfried's global network. Furthermore, at the end of April 2023, Siegfried began constructing a new global development center for Drug Substances in Evionnaz, an investment of up to CHF 25 million, which will significantly increase Siegfried's R&D capacities to drive future growth.

The DiNAMIQS acquisition creates new biotechnologies opportunities. In May 2023, Siegfried announced the acquisition of a 95% majority stake in DiNAMIQS, a Swiss-based biotechnology company focused on the development and manufacturing of viral vectors for cell and gene therapies (CGT). Siegfried intends to bring DiNAMIQS' capabilities to commercial scale and create a best-in-class biotech CDMO in that space. This will include the investment in a GMP manufacturing facility, which is currently being designed and the engineering work is in preparation. Through this acquisition, plus the follow-on establishment of commercial-scale GMP capacities, Siegfried is further expanding its footprint in the biologics space and creating significant mid- to long-term growth opportunities in this very dynamic market segment.

Oxford Biomedica Solutions expands its viral vector capabilities

2022 was a significant year for Oxford Biomedica, as the Group expanded internationally and made its first strategic acquisition, entering the larger and fast-growing adjacent AAV market.

In January 2022, Oxford Biomedica had entered into an agreement with Homology Medicines to establish Oxford Biomedica Solutions, an innovative service provider and AAV product developer with complete end-to-end chemistry, manufacturing, and controls capabilities and expertise, from pre-clinical development through to clinical drug supply. The 91,000 sq. ft. facility is located near Boston, US. The transaction completed on March 10, 2022 and was immediately accretive to the Group's revenues.

Over the last year, Oxford Biomedica has expanded its viral vector capabilities into all key viral vector types including lentivirus, adenovirus and AAV. AAV business has grown from strength to strength already, with five clients at the end of 2022, exceeding initial expectations.

With the lentiviral vector and AAV manufacturing markets poised for projected 27% and 28% CAGRs respectively from 2018-2026 (Source: Mordor Intelligence, 2021), Oxford Biomedica's expansion into the US AAV market and the growing lentivirus segment will enable success in its aim of achieving market leadership in viral vector CDMO services.

Total revenues broadly in line with last year at £140.0 million (2021: £142.8 million) due to strong performance by Oxford Biomedica Solutions, despite lower COVID-19 vaccine bioprocessing volumes. Double-digit revenue growth in the core business (excluding COVID-19 vaccine manufacturing) compared to FY 2021.

Revenues from bioprocessing and commercial development activities were maintained at £128.1 million (2021: £128.4 million). This included aggregate vaccine revenues in excess of £40.0 million.

Operating EBITDA and operating profit benefited from a profit on the sale and leaseback of the Windrush Court facility for £21.4 million.

Operating EBITDA profit was £1.6 million with an operating loss of £30.2 million (2021: operating EBITDA profit and operating profit of £35.9 million and £20.8 million respectively) due to reduced AstraZeneca vaccine production, consolidation of the investment in Oxford Biomedica Solutions investment and one-off acquisition-related due diligence costs of £5.1 million.

ROVI achieved stable total revenue of 381 million euros in the first post-pandemic half year

CMO sales increased by 4% to 172.2 million euros in the first half of 2023. For 2023, ROVI is assuming a new post-pandemic scenario in which COVID-19 would foreseeably be a seasonal disease and, in principle, the vaccine would be administered once a year. The uncertainty related to the evolution of the disease is very high. It is not, therefore, possible to make a precise assessment of the impact that this new scenario could have on the CMO business. Likewise, under the terms of the agreement signed with Moderna in February 2022, ROVI is still investing in increasing the compounding, aseptic filling, inspection, labelling and packaging capacities at its facilities and expects them to be fully installed by the end of 2024.

Samsung Biologics consolidated earning, KRW Billion

Samsung Biologics demonstrated improved profitability in both the second quarter and the first half of the year. The full utilization of Plants 1 through 3 and expanded partnerships with major pharmaceutical companies played a key role in delivering solid results.

In the second quarter of 2023, the company achieved a consolidated revenue of KRW 866.2 billion, marking a 33.0% increase on KRW 651.4 billion in the second quarter of the previous year. Operating profit reached KRW 253.4 billion, 49.4% higher than the prior-year period. Net profit for the second quarter of 2023 was KRW 184.9 billion, with an EBITDA of KRW 362.1 billion.

The first half of 2023 saw a consolidated revenue of KRW 1,587.1 billion and an operating profit of KRW 445.2 billion.

The revenue generated from Plant 4 will be reflected in the third quarter results and is expected to enhance the company's performance in the coming quarters. On June 1, the company fully completed its latest and the world's largest biomanufacturing plant, Plant 4. The move reinforces Samsung Biologics' unmatched speed and commitment in providing partners with high-quality services and products in response to the surging demand for biologics.

Building upon the recent completion of Bio Campus I, Samsung Biologics reaffirmed its commitment to meeting the increasing demand for high-quality biologics. The company unveiled its expansion plans, with the aim of commencing operations at its fifth plant by April 2025. As the first facility of Samsung Biologics' second Bio Campus, Plant 5 is expected to have the shortest construction

SAMSUNG BIOLOGICS CONSOLIDATED EARNINGS, KRW BILLION

Target name	Q2'23	Q2'22	YoY Change
Revenue	866.2	651.4	+33.0%
Operating Profit	FR 253.4	169.7	+49.4%
Net Profit	184.9	152.0-	+21.6%
EBITDA	362.1	258.6	+40.0%

Source: Samsung Biologics

timeline, and once completed will add 180,000 liters of additional capacity.

The company also expanded a number of large scale manufacturing contracts with leading pharmaceutical companies, including Roche, Pfizer, and Novartis, securing over KRW 2 trillion in sales backlog as of July, exceeding the cumulative sales backlog of the previous year.

In June, Samsung Biologics and Pfizer have announced a strategic partnership for the long-term commercial manufacturing of Pfizer's multi-product portfolio. Samsung Biologics and Pfizer entered into an initial manufacturing agreement in March 2023 for a Pfizer product. Under the terms of the new agreement, Samsung Biologics will provide Pfizer with additional capacity for large-scale manufacturing for a multi-product biosimilars portfolio covering oncology, inflammation, and immunology. Samsung will use its newest facility, Plant 4, for the manufacturing.

South Korean biotech companies are working to diversify from China in anticipation that the US could tighten export restrictions on the sector to bolster its domestic industry and curb Chinese growth, according to the Financial Times. Samsung Biologics, the world's largest contract drugmaker, has opened sales offices in Boston and New Jersey and is seeking to build plants in the US and Europe to be closer to its main customers.

Fujifilm Diosynth Biotechnologies: FY2022 (Fiscal Year Ended March 2023)

In the bio CDMO business, revenue was higher mainly due to favorable progress of biopharmaceutical contract manufacturing at the Denmark site. In June 2023, the company established Fujifilm Diosynth Biotechnologies Japan Corporation to expand the bio CDMO business in the Japanese and Asian markets. Going forward, it will accelerate business growth further by developing global and integrated operations in Japan, Asia, Europe, and the U.S.

In the life sciences business, revenue was up due to higher sales of cell culture media and strong progress in cell drug discovery support. The global market for cell culture media is expanding in line with growing demand for antibody drugs and development of advanced therapies including cell therapy and gene therapy. The company will provide strong support for R&D and manufacturing of biopharmaceuticals through its global manufacturing structure based in the U.S., Europe and Japan.

In the pharmaceutical business, revenue rose thanks to contributions from contract manufacturing of COVID-19 vaccine candidates in Japan and an upturn in demand for antibacterial agents.

In the Bio CDMO business, revenue increased mainly due to the solid performance of contract manufacturing of antibody drugs, mainly at the Denmark site. Meanwhile, slow orders for gene therapy and other drugs reflecting a difficult fundraising climate for biotech venture customers led to write-downs on components and consumables nearing the end of their shelf life.

2022 revenues show strong growth at ¥194.2 billion (up 29.2% YoY)

Q1 FY 2023: Revenue increased by 13.1% year-over-year due to higher contributions from all sub-segments, while operating income decreased by 9.1% year-over-year due to inventory write-downs in Bio CDMO and LS Solutions.

In August 2023, FUJIFILM Diosynth Biotechnologies announced a new Strategic Business Unit (SBU) structure to provide tailored support to large- and small-scale biopharmaceutical customers with high quality service and world-class performance by aligning unique service offerings and manufacturing capacities.

"We are confident this new structure will help to advance our customers' goals while also creating new, exciting opportunities for growth," said Toshi Iida, corporate vice president of Fujifilm Corporation and chairman of Fujifilm Diosynth Biotechnologies.

Successful execution of Wuxi biologics' "Follow and Win the Molecule" strategies

The revenue of the Group increased by 17.8% from approximately RMB7,206.4 million for the six months

ended June 30, 2022 to approximately RMB8,492.0 million for the six months ended June 30, 2023. The increase was mainly attributed to the successful execution of the Group's "Follow and Win the Molecule" strategies, coupled with the leading technology platform, best-in-industry timeline and excellent execution track record

The Group derived a vast majority of its revenue from customers headquartered in North America, Europe and the PRC. The fig below shows the revenue distribution by countries/regions:

For the six months ended June 30, 2023, the pre-IND services revenue of the Group increased by 6.6% to approximately RMB2,810.7 million, accounting for 33.1% of total revenue. Early-phase (phases I & II) services revenue of the Group increased by 51.8% to approximately RMB1,949.7 million, accounting for 23.0% of total revenue. Furthermore, late-phase (phase III) services and commercial manufacturing revenue of the Group increased by 14.3% to approximately RMB3,603.3 million, accounting for 42.4% of total revenue, by implementing the "Follow and Win the Molecule" strategies.

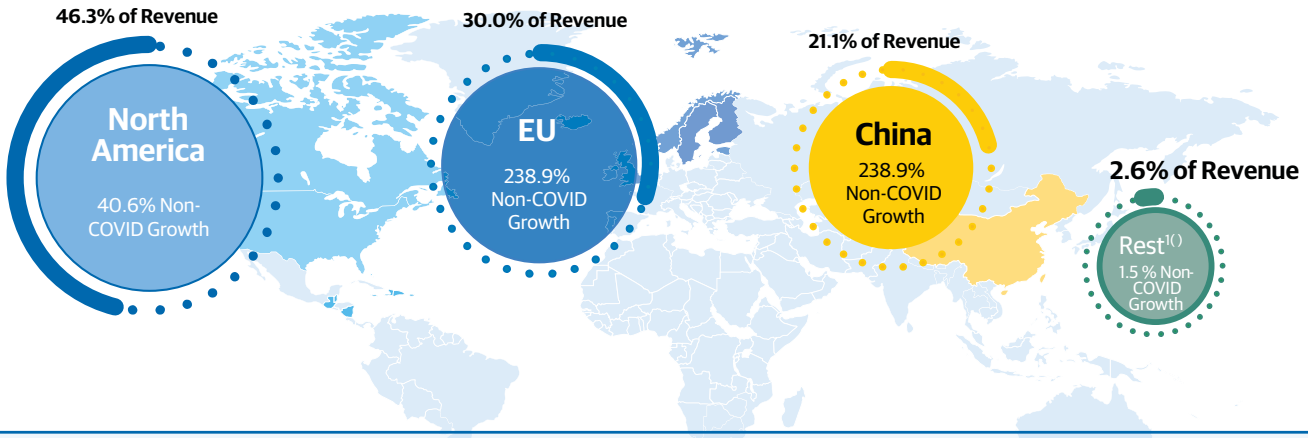
The Group's revenue for the six months ended June 30, 2023 increased by 17.8% year-on-year to RMB 8,492.0 million, together with a 4.3% year-on-year growth in gross profit to RMB 3,560.6 million and a 0.4% year-on-year growth in adjusted net profit to RMB 2,925.6 million, while maintaining positive free cash flow.

The Group's total backlog, including the service backlog and upcoming potential milestone fees, also increased from US$18,467 million as of June 30, 2022 to US$20,108 million as of June 30, 2023

The total number of integrated projects increased from 534 at the same time last year to 621 as at June 30, 2023, including close to 580 non-COVID integrated projects, demonstrating the Group's strong business growth even without COVID-19 projects

The number of late-phase (phase III) projects and commercial manufacturing projects leaped from 43 at the same time last year to 66 (44 in late-phase and 22 in commercial manufacturing) as at June 30, 2023 ■

WUXI BIOLOGICS - SUSTAINED GROWTH WITH DIVERSE DRIVERS



- North America: the biggest market with growth potential. Non-COVID revenue grew by 40.6% YoY and over 60% of new projects were added from this region in 1H 2023, expecting more growth drivers to fuel sustainable growth
- Europe: the market with the fastest growth rate. Non-COVID revenue grew by 238.9% YoY. Extended more collaboration with MNCs and biotech in EU and expect continued strong performance from EU market
- China: achieved 22.7% non-COVID revenue growth and collaborated more with high-quality clients, especially those who licensed out the products to global MNCs, partially offset by the impact from biotech funding constrains
- Rest of the World: continued to enable customers in this region and explored more collaborative opportunities

Source: Wuxi
Note:1. The rest market primarily includes Singapore, Japan, South Korea, Australia and Israel

UNITHER PHARMACEUTICALS

30 years

+100 COUNTRIES WHERE PRODUCTS ARE SOLD IN

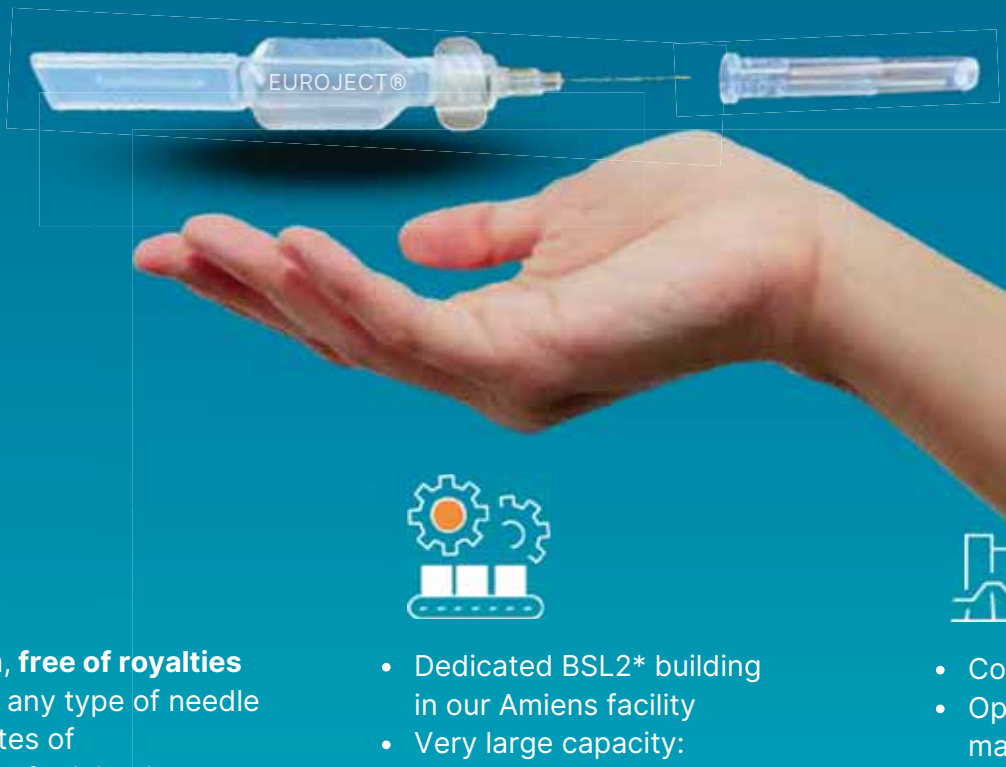
Global subcontractor

WORLDWIDE LEADER IN THE DEVELOPMENT AND MANUFACTURING OF BLOW-FILL-SEAL (BFS) VIALS

Approved by top health authorities

Introducing a new way to inject therapeutics

EUROJECT®



This prototype device might be subject to changes. Proprietary information of Unither Pharmaceuticals.

- Open system, **free of royalties**
- Adaptable to any type of needle
- Different routes of administration for injection

- Dedicated BSL2* building in our Amiens facility
- Very large capacity: up to 1 billion doses/year
- No risk of shortage in components and capacities

*Biosafety level

- Competitive pricing
- Opportunity for new markets (LMIC*)

*Low middle income countries

LEARN MORE

+33 (0) 1 44 63 51 70 contact@unither-pharma.com www.unither-pharma.com

UNITHER PHARMACEUTICALS 30 years

EUROJECT®

NEW INJECTION DEVICE

Euroject® could be the game changer for healthcare professionals' (HCPs) practice

More than 2/3 HCPs would be ready to use Euroject® new injection device

7/10 of HCPs find Euroject® injection device relevant for vaccines

1/2 of the respondents find it relevant for pain medications

4/5 of HCPs perceive Euroject® device as an innovative product

2/3 of the respondents seem confident with the use of Euroject®

3/5 of HCPs think Euroject® can be beneficial for their practice

THE MAIN ADVANTAGES OF EUROJECT®

(vs pre-filled syringes or self-filling syringes):

1 Easy to use device

2 A time saving process

3 Limited handling (less preparation)

Geographical scope: France, UK, Italy • Targets per country: GPs (n=50), Pharmacists (n=50), Nurses (n=50)
Fieldwork: 22nd Dec 2021 – 14th Jan 2022 • Study conducted by Potloc

WHERE TO MEET US NEXT?

PDA
17-18 oct. 2023
Gothenburg, Sweden
Booth #37

CPhI
24-26 oct. 2023
Barcelona, Spain
Booth #3R26

CONTACT US

+33 (0) 1 44 63 51 70
contact@unither-pharma.com
www.unither-pharma.com

LEARN MORE

Medicines
The Great Shortage:
In search of solutions

Since the end of 2022, EU countries have been reporting serious problems in sourcing certain important medicines. Such shortages are not new, but their exponential increase over the past few years, and especially since 2022, has hit patients hard.

In its January issue, PHARMAnetwork published an analysis of the various factors involved in the disruptions to one of the most complex supply chains in the world: "Headed for the Great Shortage? In search of the real reasons"

Following this analysis, several letters were received from CDMO CEOs proposing avenues for reflection to overcome the problems of stock shortages, and the strategies they had implemented within their companies to help resolve medication shortages in their areas of activity.

PHARMAnetwork is publishing the first letters we received in this issue of the magazine.

www.pharmanetwork.digital/html5/reader/production/default.aspx?pubname=&edid=5c72ed74-571f-45d1-8fdb-4428b38c9f04&pnum=36

Author: **Jean-François Hilaire**
CEO of Unither Pharmaceuticals

REPORT

Investing in production capacity

Creating a predictable framework that will allow pharmaceutical manufacturers to invest in production capacity ahead of immediate demand.

Traditionally, in Europe, authorities have regulated pharmaceuticals from a quality standpoint with Good Manufacturing Practices (GMP) and from an economic standpoint with various price-setting schemes. Despite GMP regulations being unified, the price settings vary, which results in confusion about distribution channels and in economic constraints for certain products. Furthermore, competition with generics has generated a need to reduce production costs, which has been achieved by consolidating worldwide demand for a given product or intermediate in a limited number of supply centres, often located in low-labour-cost countries, principally China. This has resulted in an increasing number of drug shortages over the last years, reaching a peak during and after the Covid-19 pandemic, although the supply of Covid-19 vaccines in Europe (manufactured in Europe, incidentally) has been remarkably efficient.

Economic constraints faced by drug manufacturers

New hurdles lie ahead for manufacturers. For instance, implementing Annex 1 to the European GMP regulation and increasing requirements more generally from various regulations may require them to make massive investments in production facilities that they may not be able to afford. This will result in the obsolescence of a large number of sites. Meanwhile, environmental sustainability will limit our access to water and the possibility of erecting new buildings, as well as increasing energy costs. These measures are legitimate, as they are part of our responsibilities as entrepreneurs, but the economic framework in which pharmaceuticals are produced will not allow all players to cope with so many constraints.

Relocating pharmaceutical manufacturing to Europe

To allow pharmaceutical manufacturers to invest reasonably in production capacity ahead of their immediate needs, a genuine policy is needed for relocating pharmaceutical manufacturing to Europe, with support for access to land and utilities and with predictable regulatory and economical terms, enabling companies to build facilities and connect to utilities within a predictable regulatory and economic framework. In order for this to be successful, it should be combined with reasonable drug pricing schemes, governmental support with capital to ease investment, and access to qualified staff, otherwise it will take decades to be implemented, if indeed it happens one day at all.

Such initiatives should not be limited to critical medicines. It is also important to make sure that innovative treatments that are developed in Europe with tax relief support from various member states remain in Europe for their commercial production. As this assumes investments in facilities by various industry stakeholders, this would also require governmental incentive measures.

The CDMO's mission: delivering the ordered product quantities at a competitive price

In the short term, in addition to the structural measures suggested above and reporting of drug shortages, ensuring transparency around available inventories for a given product throughout Europe for Marketing Authorization holders would allow them to keep much tighter control over their supply chain and forthcoming demand. This information can then be transferred digitally to their suppliers, namely us as CDMOs. As a CDMO, our mission is to deliver the quantities of products ordered by our customers at a competitive price. This means that we need access to all the required components (active ingredients, excipients, packing materials) on the one hand, and adequate utilisation of our production assets with ideally stable and predictable demand, on the other. Production sites located in Europe could then react swiftly to any change in demand within such a controlled frame.

Additionally, authorities might think about a specific regulatory process to allow swift change when there is an urgent need. This could be to substitute a component that becomes unavailable or following an accident, such as the storm that shut down the Pfizer US site in North Carolina in July 2023.

To conclude, Europe is a prime location to develop and manufacture pharmaceuticals for domestic needs, as well as for export. Creating a favourable environment for entrepreneurs in this field is not only addressing a healthcare necessity, but also preparing the future for the next generations, a long-term endeavour.

Author

Stéphane Lepeu

Delpharm Chief Commercial Officer

Supply resilience and an incentive to produce locally

Drug shortages are clearly multi-factorial. As far as the production of medicines is concerned, common-sense measures need to be taken by both the authorities and the CDMOs to ensure availability, particularly for mature medicines.

The challenge of drug shortages highlights the importance of four fundamental issues in guaranteeing a continuous supply of pharmaceutical products. As the current crisis highlights these challenges, it is imperative to take action to ensure a robust and resilient pharmaceutical industry.

Economic

The economic equilibrium of the pharmaceutical industry is a complex challenge at a time when most countries are having to take steps to reduce their deficits. It is crucial to find a way of remunerating both mature products and innovations, in order to ensure a sustainable and balanced pharmaceutical industry. However, the level of prices for mature products has had an impact on European CDMOs, which have not been able to invest enough in the production capacities of mature medicines. This is particularly the case for dry forms, given the global overcapacity in this segment. Innovative medicines priced at €5,000 a box are rarely out of stock, unlike mature products sold for just a few euros.

Strategic challenge

The Covid 19 pandemic revealed the need to enhance healthcare independence by repatriating the production of active ingredients and strategic medicines. This relocation aims to avoid disruption to the supply chain and guarantee access to essential medicines in times of crisis. This strategy must be supported by incentives and European cooperation.

Environmental challenge

It is also essential to make a significant reduction in the environmental footprint of the pharmaceutical industry. Decarbonisation is imperative, even if the challenge is significant because any change of process is complicated for the pharmaceutical industry.

Recruitment issues

Like many industrial sectors, the pharmaceutical industry faces recruitment challenges. The complexity of the manufacturing processes requires a significant amount of training time, making it crucial to strengthen apprenticeship and continuous training programmes. Attracting and training new talent is imperative to maintain production operations.

Suggestions for action at government level:

1. Investment in production: The authorities must support investment in pharmaceutical production infrastructures. Financial incentives, such as the European Union's participation in major investments or tax exemption mechanisms at national level, will help to improve production capacity.

2. Bonus-malus system: The introduction of a bonus-malus system for reimbursements for medicines prescribed in Europe would encourage more environmentally friendly production. Products manufactured with electricity generated using carbon-free energy would be rewarded with slightly higher reimbursement prices, while those using less sustainable energy sources would be penalised.

3. Promoting Local Production: A similar bonus-malus mechanism would encourage local production in Europe, reducing transport costs and strengthening the resilience of the supply chain.

These last two measures have the advantage of not increasing health system deficits.

The Delpharm example:

Delpharm illustrates these challenges by taking proactive measures. The company has contributed to the fight against the Covid pandemic by filling a leading vaccine and providing urgent production of essential medicines in short supply, such as Cisatracurim. Massive investment of around 8-10% of annual sales in renewing production lines and expanding capacity illustrates the company's commitment to the long-term viability and reliability of its industrial facilities.

To anticipate current fluctuations in demand more effectively, Delpharm is also optimising production planning with its customers by implementing improved S&OP processes.

In terms of recruitment, the use of apprenticeships has been significantly increased, and in many cases serves as a form of pre-recruitment.

Conclusion:

Drug shortages are a complex challenge requiring multifaceted solutions. By tackling the economic, strategic, environmental and recruitment issues, CDMOs, with the support of the authorities, can contribute to a resilient and sustainable pharmaceutical industry in terms of patient supply.

Author:
Bruce Vielle
Synerlab group CEO

REPORT

Supporting industrial production in the pharmaceutical industry is an essential issue for France's health autonomy

Synerlab is at the heart of the French government's stated desire for greater self-sufficiency in health.

Synerlab produces nearly 10% of the 450 drugs designated as essential by the government, and we have a site dedicated to the production of generics. We have more than 1,000 employees in France, which places us in the country's TOP 5 in contract manufacturing. However, our group has not escaped the relocation movement over the last 10 years. We have been forced to shut down two Amoxicillin production workshops and are experiencing the departure of certain production activities for lower-cost countries. Why?

The low sale prices of essential products are the main cause of pharmaceutical production relocations:

Firstly, as we are in a price-regulated market, any reduction in sale prices combined with an increase in our purchasing and labour costs prevents us from maintaining certain production activities. Pharmaceutical, environmental and social regulations are becoming more stringent and generating additional costs that it is difficult for us to absorb, despite productivity and continuous improvement policies. Thus, some product lines become loss-making. Sometimes the cost prices even exceed the selling prices. We are caught in a spiral of stopping the least profitable production to move towards production with higher added value. Stopping some production activities is therefore a question of survival for our companies, a decision which is not always linked to the country's strategy of self-sufficiency in essential specialties. This is the case of products such as Amoxicillin, paracetamol and many others.

Synerlab is a member of CDMO France and works transparently with the association of French contract manufacturers to raise collective awareness of the real issues. An increase in sale prices and/or massification of production across the country are appropriate responses. Synerlab is ready to start up its Amoxicillin production workshops again and make them operational within 18 months if the public authorities decide to adjust sale prices upwards. Likewise, we have the know-how to increase the production of around thirty essential medicines.

Customers and public authorities must give us medium-term visibility to secure our investments:

The second issue is investment. Every investor needs good medium-term visibility to invest in new production lines and the instability of the pharmaceutical market is not reassuring for them at the moment. At the same time, growing regulatory constraints in Europe have increased the levels of investment required, as well as the implementation times. A year of decision-making time is soon lost and cannot be made up for. For some equipment, it takes 24 to 30 months from the moment of the decision through to the first compliant product. Suffice it to say that capacity and shortage problems can hardly be resolved in 6 months. To reassure our investors, we need visibility and speed in the decision-making of regulatory authorities.

Over the past few years, Synerlab has been proactive in terms of investment. We have invested in capacity in freeze drying, sterile multi-doses, sterile isolators, and primary and secondary packaging machines for dry forms. In future years, we plan to keep up the pace of investments to follow the growth of our customers. We are exploring the possibility of sharing capacity investments as a way of diluting risk. We have benefited from state aid and continue to work in this respect to support the health sufficiency strategy. Overall, it is appropriate to work more closely and collaboratively across the entire value chain up to the French State.

Improving the attractiveness of our production professions is essential for the sustainability of our high value-added sector in France:

Finally, the last key reason concerns the attractiveness of our professions. The pharmaceutical industry is no longer a dream and must reinvent its management style and digital tools to attract young people and talents. It is still a question of investments, but also of management and leadership, team empowerment and work atmosphere.

Synerlab promotes the diversity of its employees, a managerial powerhouse that unites its teams and contributes to Synerlab promotes the diversity of its employees, a managerial powerhouse that unites its teams and contributes to the performance of the company. We have also undertaken the digitalization of our HR processes, which must be both a source of attractiveness and overall productivity.

In conclusion, better coordination with Public Authorities, increased visibility for our investors, and the continuity of HR transformations will consolidate our business in France, which is essential to the country's health self-sufficiency.

Author: **Carole Delauney**
Senior Director Business Development, ten23 health

Thinking global, acting locally

Smaller and nimble drug product development and manufacturing players could make a difference.

We are living in the Anthropocene, where human-made changes to the planet have led to certain challenges, including the climate catastrophe, but also the surge in viral pandemics. We live in a VUCA world, i.e. a world full of volatility, uncertainty, complexity and ambiguity.

Self-control of research in the pharmaceutical industry is essential, as well as Supply Chain management from end-to-end.

The COVID pandemic has benefitted from years and decades of science that finally allowed the generation, manufacture and distribution of vaccines in record time.

Yet, it also clearly showed the volatility of the pharmaceutical supply chain, global interdependencies and complexity of the pharmaceutical sector as a whole. It evidenced the differences that exist between the Global North and Global South.

Collaboration from different actors is essential

Generally speaking, I believe the pharmaceutical sector would benefit from more agility and flexibility. Smaller, nimble players can play a significant role here, in combination with the funding, longevity and reach of large pharmaceutical companies. The sector would benefit hugely from more thorough supply chain assessments, highlighting risks also in the secondary and tertiary supply chains, and risk management plans to cope with specific situations like pandemic crises. We require more collaboration between pharmaceutical companies and CDMOs, and between the private sector and governments, regulators and NGOs. We need to shift our focus from "global production and sourcing" based on financial considerations to "global supplies" - supplying the world, including the Global South.

Incentification focused on money seems a prehistoric strategy

This will require rethinking of classical supply chain and just-in-time models and healthcare economics. The incentification of pharmaceutical products should not be based purely on price, leading to moving the production of medicines into low cost countries. Our experience during the COVID pandemic clearly showed the weakness of such a model. Other considerations, including the ability to supply (essential) medicines locally, and the consideration of positive societal and environmental impact, should be considered equally. As a development, testing and manufacturing partner, ten23 health is developing a sustainable approach with a focus on small-to-medium scale demand aligned with specific supply chain requirements. C(D)MOs have developed local offers adapted to specific demands. Industry players should embrace differences and options developed in response to the diversity of market demand. Cost will always be a driver, but offering quality plus flexibility in time and the quality supplied is priceless: focusing on a number only is to underestimate the value suppliers can bring, unfortunately.

Could regulatory bodies align one step further?

Additional benefits could materialize by further aligning regulatory requirements globally, which would definitely have a positive impact on access to medicines and encourage industry players to offer global solutions, which would be a win-win in the end.

In summary, I believe we can only meet tomorrow's challenges in this pharmaceutical sector in a VUCA world through partnerships between all players, from large pharma to CDMOs, NGOs, distributors, regulators, governments and payers.

CDMOs will surely play a vital role, especially those with agility and flexibility in their DNA.

Author:

Javier López-Belmonte

Vice President and General Manager of Industrial Operations and Finance at ROVI

REPORT

ROVI, a CMO moving forward

Focused on continuing to invest and grow, accompanied by those who place their confidence in our twenty-five years' experience in filling biotechnological products and vaccines.

The pandemic crisis caused by COVID-19 demonstrated, among other factors, Europe's dependence on other countries, mainly in Asia, for access to essential medicines. This has encouraged the pharmaceutical industry in Europe to seek new and innovative alternatives and solutions that allow it to depend less on other countries and be able to ensure a self-sufficient strategic response to demand in the healthcare area.

ROVI, as a company engaged in the research, development, and manufacture of both its own products and those of others, bases its business project on helping to improve people's health, with a commitment to the company's vertical integration as one of its strategic pillars. Our manufacturing activity takes place in the seven plants we have in Spain, which are fully integrated and specialised (tablets, sachets, vials, and prefilled syringes). This has led us to become one of the principal companies in the CMO business and a world leader in prefilled syringe production, currently exporting our products to over 50 countries, with international sales that accounted for 98% of our business in 2022.

Over recent years, we have been committed to increasing ROVI's operating capacity for both aseptic filling and packaging, so as to offer our current and potential future customers more -and more efficient - lines that have a higher response capacity. This expansion started in parallel with the project to fill Moderna's COVID-19 vaccines, showing our flexibility when adapting to the new challenges and our customers' needs without jeopardising either our service quality or our commitments.

We have built new facilities in record time to house new lines with the latest aseptic filling and plastic-free packaging technologies. Thus, ROVI is committed to reinforcing quality manufacturing in Europe, positioning itself as an industry leader and evolving towards more sustainable manufacturing, investing, together with its partners, in solutions that are more respectful of the environment.

Rovi's Strengths

As one of the strategic pillars in the CMO business, we can offer all the knowledge and know-how that come from 25 years of experience in the aseptic filling of syringes and vials with biotechnological products and vaccines. In a Europe that is seeking to recover production processes and technologies, ROVI offers technological solutions that meet the highest quality standards for the aseptic filling of syringes and vials, as well as the inspection and secondary packaging of biotechnological products, biosimilars, vaccines, etc., for both large corporations that need to increase the capacity for their key products and medium-size and small companies who seek a solid group in which to place their confidence.

All ROVI's industrial operating capacity is in the Madrid area, where the company has high manufacturing capacity. We currently have ten aseptic filling lines for the main suppliers worldwide (Marchesini, Bausch Stroebel, Groninger, Optima, Dara, etc) and we plan to increase our secondary packaging capacity in the near future, with the start-up of the twelfth and thirteenth packaging lines with Dividella technology, offering plastic-free blister packing for injectables. Our intention is to be ready to tackle the challenges that arise over the next few years through our commitment to top-quality manufacturing and service in Europe. Proof of this is that ROVI is currently approved by the major international organisations, such as the FDA, PDMA, Aemps, Anvisa, etc.

Towards the Future

According to GlobeNewswire, the global market is expected to grow 7% between 2022 and 2027 due to the increasing trend among pharmaceutical companies to outsource their production activities. In this respect, ROVI has been in the business for over 25 years and has become a sector leader. With more than 1,500 people in the industrial area and still growing, ROVI is committed to European technological development, with a steady rate of investment to increase capacities and enhance the capabilities already installed in order to provide an optimal service and respond to market needs, always focusing on the same subject: the patient.

Now, more than ever, in this context marked by uncertainty, experience and know-how are essential in providing the customer and, therefore, the patient with the best solution. Reinforcing investment and growing in and with Europe could well be the key.

Authors: **Sophie Vo & Sally Shorthose**
Bird & Bird

Regulatory
EU Commission's proposed changes
to marketing authorisation procedures

*As medicinal products are not permitted to be placed on a market until the marketing authorisation ("**MA**") for that market is obtained, the procedural aspects of applying for and obtaining MAs are a material hurdle to obtaining market access and making products available to patients.*

As part of the European Commission's proposed revisions to the pharmaceutical legislative framework, announced on 26 April 2023, changes have been suggested to the MA application procedure to improve timely and equitable access to medicines and security of supply, to promote innovation, to make medicines more environmentally sustainable and to address antimicrobial resistance, pursuant to the European Commission's stated main objectives in its Press Release.

What are the current procedures?

Under the current Directive 2001/83/EC on the Community code relating to medicinal products for human use ("**Directive**") and Regulation (EC) No 726/2004 ("**Regulation**") laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, there are two main routes for obtaining MAs:centralised; and national.

Under the centralised authorisation procedure, which is compulsory for certain medicines (including those containing a new active substance to treat HIV, cancer, diabetes, neurodegenerative disease etc), a single MA application is made to the European Medicines Authority ("**EMA**"). The EMA makes a recommendation to the European Commission about whether a MA should be granted, and the European Commission makes a legally binding decision based on the EMA's recommendation. The centralised MA that is granted by the European Commission is then valid in all EU Member States as well as the European Economic Area countries (Iceland, Liechtenstein and Norway). For more detail about the calendar for the assessment process, see the EMA's From laboratory to patient: the journey of a medicine assessed by EMA.

In comparison, applications made under the national authorisation procedure is specific to each EU Member State, although some Member States may adopt mutual recognition of MAs granted in other Member States.

What are the proposed changes?

The proposed revision of the pharmaceutical legislation consists of repealing and replacing both the Directive and

Regulation; however, the general principles of the centralised procedural would be maintained.

Proposed changes to the centralised procedure for obtaining an MA include the following:

- The scope of medicines that are required to go through the centralised procedure will be extended to **antimicrobial medicinal products and products seeking paediatric use**.[1]
- The timeframes for completing various phases of the MA application process will be reduced. Notably, the deadline for the CHMP to assess the MA application and issue its opinion as part of the centralised procedure will be **reduced from 210 to 180 "active" days** from receipt of a valid application.[2] Member States will likewise be required to ensure the procedure for granting a MA under the national procedure is completed within a **maximum of 180 days** from receipt of a valid application.[3]
- The circumstances in which the European Commission may authorise duplicate MA applications as part of the centralised procedure will be limited to where one of the medicinal product's "indications or pharmaceutical forms is protected by a **patent or a supplementary protection certificate** in one or more Member States" (but the initial or duplicate MA must be withdrawn once the IP right expires) or "for reasons of co-marketing with a different undertaking not belonging to the same group as the marketing authorisation holder of the medicinal product".[4]
- There will be greater scope for centralised MAs to be granted under **exceptional circumstances** for a new therapeutic indication for an existing MA, as **conditional MAs** where there is an unmet medical need or with **post-authorisation study** requirements (such as, safety, efficacy and environmental risk assessment studies).[5]
- Instead of a 5-year duration, a centralised MA (not granted under exceptional circumstances or conditionally) will be valid for an **unlimited period** with the possibility for the Commission to decide to limit the validity to 5 years where there are safety concerns.[6]
- **Temporary emergency marketing authorisations** will be available during public health emergencies to enable faster availability of the medicinal product.[7]
- MA applications will be required to be submitted electronically under both the centralised and national procedures,[8] consistent with objective for wider use of electronic processes to reduce administrative burden.
- Additional information will need to be provided with the MA application, whether under the centralised or national procedure, including an environmental risk assessment (see our article on the strengthened **environmental risk assessment** requirements) and an **antimicrobial stewardship plan** (for applications concerning an antimicrobial medicinal product - see our article on the proposals to fight against antimicrobial resistance), lack of which could result in the refusal of the application. There are also specific requirements for Paediatric Use MAs (see our coverage of the proposed reform for paediatric medicines here).[9]
- An **active substance master file** for a chemical active substance of a medicinal product, or **additional quality master file** for an active substance other than a chemical active substance, will be introduced as options for submission in place of providing all the relevant data each time an assessment is made. The objective is to provide for a single assessment of the active substance by issuing a certificate, thus minimising duplication of processes.[10]
- Centralised MA holders will have obligations to **monitor and prevent shortages** in the availability and supply of medicinal products; e.g., by keeping a shortage prevention plan in place (see our article on the proposed reforms relating to the prevention of shortages of medicinal products).[11]

We will continue to monitor the proposed revisions closely for changes as the European Commission's proposals progress through the EU legislative process. ■

Sophie Vo
Associate in the Intellectual Property Group in London with a particular focus on the life sciences and healthcare sectors.

Sally Shorthose
As one of Bird & Bird's most experienced intellectual property partners, specializing in transactional IP matters.

1 Article 3(1) and Annex I Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 ("Proposed Regulation").
2 Article 6(6) Proposed Regulation.
3 Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC ("Proposed Directive").
4 Article 25 Proposed Regulation.
5 Articles 18-20 Proposed Regulation.
6 Article 17(1)-(2) Proposed Regulation.
7 Section 3 Proposed Regulation.
8 Article 5(3) Proposed Regulation; article 6(1) Proposed Directive.
9 Article 6(2) and Annex I Proposed Directive.
10 Articles 25-26 Proposed Directive.
11 Article 117 Proposed Regulation.

Authors: **Anna Koster, Hester Borgers, Sarah Faircliffe**
Bird & Bird

Proposed reform of the EU pharmaceutical legislation:

New regime for orphan medicinal products under the proposed regulation

As part of the revision of the EU pharmaceutical legislative framework, a new regulation is proposed, which will replace, among others, Regulation (EU) 141/2000 on orphan medicinal products. According to the European Commission, the current legislation on orphan medicinal products no longer meets the needs of both patients and the pharmaceutical sector, with 95% of the 6000+ recognised rare diseases having no treatment option[1]. Below we set out the main changes in the proposed regulation.

Regarding the criteria for orphan designations, the prevalence criterion (not more than five affected persons per 10.000) is maintained as the appropriate threshold under the proposed directive. However, as this criterion is not appropriate for all rare diseases, the European Commission will be able to set up specific designation criteria for certain conditions with, for example, a short duration and high mortality rate. The additional "no satisfactory method" (or alternatively establishing "significant benefit" over existing methods) criterion also remains in place. The previous alternative criterion that medicinal products will likely not generate a sufficient return on investment in order to qualify for an orphan designation has been omitted from the proposed directive. Another change is that the current unlimited validity of the designation is proposed to be limited to 7 years (with the possibility of an extension).

The European Commission aims to adopt a new framework for market exclusivity of variable duration, replacing the (in principle) 10-year market exclusivity for orphan medicinal products. According to proposed article 71(2)(a), the market exclusivity for orphan medicinal products will last for nine years in principle. However, orphan medicinal products addressing a high unmet medical need will have market exclusivity for 10 years (article 71(2)(b)) and orphan medicinal products which have been authorised based on bibliographic data according to article 13 of the proposed new regulation will have a 5-year market exclusivity (article 71(2)c)). For new therapeutic indications of orphan medicinal products referred to in 71(2)(a) and (b), the market exclusivity can be prolonged by twelve months for each of the first two new indications in different orphan conditions; these new indications must be authorised at least 2 years before the end of market exclusivity. The market exclusivity can also be extended for a further year based on meeting certain supply obligations in all Member States. The criteria to derogate

from market exclusivity remain the same as in the current legislation. Where a marketing authorisation holder holds more than one orphan marketing authorisation for the same active substance, these authorisations will not benefit from separate market exclusivity periods.

The European Commission's aim is that the new market exclusivity framework will improve competitiveness and reduce prices, offering manufacturers of generics and biosimilars opportunities for faster market entry for their products. The proposed regulation attempts to achieve this with article 71(6), which ensures that the application for a marketing authorisation for similar medicinal products is not prevented by market exclusivity of orphan medicines, if the remainder of this market exclusivity is less than two years.

According to article 73 of the proposed regulation, the working arrangements referred to in the new fee regulation will set out total or partial reductions for EMA fees related to orphan medicinal products. Other support for orphan medicinal products development, by means of scientific and regulatory advice, will be further strengthened under the proposed regulation. According to article 60(1)(b), the EMA can offer enhanced scientific and regulatory support for orphan medicinal products which are likely to address a high unmet medical need. ■

Anna Koster
As an associate in our Intellectual Property Group, based in our Amsterdam office, I offer our clients an all-round IP practice.

Hester Borgers
As an associate in our Intellectual Property Group in Amsterdam, I specialise in patent law and life sciences regulatory and bring my passion for technology to the fore when I'm advising our clients on their matters. My experience includes patent litigation and regulatory advice, the latter focused on both the life sciences industry as well as the food industry. As a member of Bird & Bird's Life Sciences and Healthcare Group, I work daily on complex cross-country cases together with our other offices. I have experience in complex patent litigation, with a strong focus on the medical devices industry and pharmaceutical sector.

Sarah Faircliffe
Legal Director in Bird & Bird (London) LLP.

As a member of our International Life Sciences Group, I specialise in European regulatory law concerning medicinal products, medical devices and related areas. Bringing a wealth of industry and policy knowledge to my role here at Bird & Bird, I offer unique insight into the law and procedures concerning the regulation of medicines, having spent 10 years as Legal Adviser with the European Medicines Agency (EMA). During my time at the EMA, I advised on many areas, including orphan drugs, paediatrics and generics of centrally authorised products, as well as advising the EMA's scientific committees on legal issues.

1 Impact assessment report accompanying the revision of the medicines for rare diseases and children legislation, SWD – IA – OP revision_RSBv 27102022 (europa.eu).

Authors: **Phillipus Putter, Sarah Faircliffe**
Bird & Bird

What does the European Commission's proposed reform of EU pharmaceutical legislation mean for Paediatric medicines?

Reforming legislation is rarely a straightforward task. In the context of legislation governing medicines, countless stakeholders have a diverse range of interests and ambitions: patients need to be protected, and all without stifling future research and development. The European Commission's proposed reform of European pharmaceutical legislation introduces several important changes to the way paediatric medicinal products (PMPs) are regulated in the EU in terms of the requirements and incentives to study medicines in children.

There are two main legislative provisions before the Commission: a new Directive (replacing 2001/83/EC and 2009/35/EC) and a new Regulation (replacing 726/2004, 1901/2006 (the Paediatric Regulation), and 141/2000/EC). Chapter VII of the proposed new Regulation sets out procedural requirements concerning the agreement and management of Paediatric Investigation Plans (PIPs), including deferral and waiver schemes. Obtaining a product or class waiver for diseases/conditions occurring only in adults becomes more limited as this will not cover situations where the product has the same mechanism of action in children, even in a different condition in the same therapeutic area, as in treatment of the adult condition applied for. Provision for a "Paediatric Use Marketing Authorisation" (PUMA) is maintained in the draft Regulation. The possibility of submitting a simplified "initial" PIP in specific cases is introduced, but overall PIP scrutiny is strengthened..

Rewards for the completion of PIPs are set out in the proposed new Directive. This specifies when marketing authorisation applications will need to contain the results of a completed PIP (or evidence of an agreed waiver/deferral); variation applications covering new strengths of authorised products covered by a SPC or a patent qualifying for a SPC are newly included, as are "hybrid" applications for such products. The proposal also contains specific provisions on checking PIP compliance and on the data derived from PIPs and sets out the rewards for PIP compliance; the current six-month supplementary protection certificate (SPC) extension reward is maintained (provided that a 1 year market

protection extension is not obtained for the new indication), but the current separate 2-year market exclusivity extension for orphan medicines has been abandoned so the SPC extension will now also apply to orphan products (we discuss the new orphan incentive proposals here). This could give originator companies a total of up to five and a half years of additional protection via an extended SPC.

Many of the new proposals are born out of the Commission's 2020 evaluation of medicines for rare diseases and children, which paved the way for legislative reform; revealing that, although the Paediatric Regulation fosters development and availability of PMPs, there is inadequate development in areas where the need for medicines is greatest (i.e. products for less profitable therapeutic needs). This problem is not new or limited to PMPs (see for example orphan drugs, which are also incentivised in the new legislation).

The Commission intends to streamline various measures and obligations, aiming to reduce patient access time by two to three years and commercialising at least three paediatric products every year. The Commission claims that originator companies would gain EUR103 million annually in gross profits by developing new PMPs. The Commission also believes that generics will benefit from the simplification of the rewards scheme because it will be easier to predict when their products could, in theory, enter the market. As with all new legislation, the proof is in the pudding.

The Commission believes that the revised incentives will lead to an increased number of medicinal products (in particular where there is an unmet clinical need) which are expected to reach the bedside faster than under the current legislation. ■

Phillipus Putter
I am an associate in the Intellectual Property Group based in London. I work with clients on a wide spectrum of intellectual property rights, with a particular focus on patent litigation and enforcement. I have a broad range of contentious and non-contentious experience across all intellectual property rights. Although my main area of focus is patent litigation, I also have a keen interest in trademarks and design rights. My experience includes providing regulatory advice in relation to pharmaceuticals and medical devices, including marketing and advertising of medicinal products in the UK and EU.

Sarah Faircliffe, Legal Director in Bird & Bird (London) LLP.
Please see page 59 for bio.

Authors: **Sarah Faircliffe, Nour Saab, Johanna Harelimana**
Bird & Bird

Reform of the EU pharmaceutical legislation: proposals to fight against antimicrobial resistance

As mentioned in our previous article, the European Commission finally presented on 26 April 2023 its long-awaited plan revising the European pharmaceutical legislation, the so-called "Pharmaceutical Package", including both a Directive and a Regulation proposal. The legislative proposals are accompanied by a Recommendation from the Council of the European Union (EU) addressing antimicrobial resistance, ***one of the main focuses of this new legislative framework.***

Indeed, **"antimicrobial resistance"** (AMR) has been identified as one of the three main health threats targeting the EU[1]. AMR is the ability of a micro-organism to survive or to grow in the presence of an antimicrobial agent that is usually sufficient to inhibit or kill that micro-organism; in other words, the ability of micro-organisms, such as bacteria, to become increasingly resistant to an antimicrobial to which they were previously susceptible.

Referred to as the "silent pandemic", AMR is thought to be responsible for 35,000 deaths a year in the EU/EEA[2] and entails considerable expenses for healthcare systems. The number of new, more effective anti-microbials in development is concerningly low and there has been much debate about the best format for EU-wide structured incentives (as have been adopted in some Member States) to help encourage companies to invest in developing anti-microbial products.

The draft revision of EU pharmaceutical legislation sets out several complementary measures to tackle the rising problem of AMR:

The Regulation proposal: a voucher system granting transferable data exclusivity rights to encourage the development of antimicrobials

Chapter III of the draft regulation (articles 40 to 43) introduces a system of financial rewards for developers of new "priority" antimicrobials, through the granting of a **transferable data exclusivity voucher.**

It should be noted that this is a temporary mechanism to be tested for a period of up to fifteen years. The number of vouchers granted over this period is restricted to a

maximum of ten, to curtail the potential burden this scheme could have on healthcare systems.

The Directive proposal: various measures to promote the prudent use of antimicrobials

Related measures are introduced within the framework of the Directive, including:

- inclusion of an "antimicrobial stewardship plan" when applying for a marketing authorization and adaptation of the pack size of the antimicrobial to the usual posology and duration of treatment (article 17);
- extension of the scope of the environmental risk assessment (required for the granting of a marketing authorisation)[3] to cover the risk of AMR selection in the environment due to the manufacturing, use and disposal of the medicinal product (article 22);
- classification by default of antimicrobials as prescription-only medicinal products (article 51);
- inclusion in the packaging of an "awareness card" containing specific information on the antimicrobial, AMR and the appropriate use and disposal of antimicrobials (article 69).

The Council recommendation: a coordinated response to the cross-cutting, cross-border issue of AMR

On 13 June 2023, the Council adopted a recommendation aimed at combating AMR in the fields of human health, animal health and the environment. This recommendation is an extension of the EU "One Health" action plan, and provides Member States with concrete objectives and means of action, in particular to:

- implement national action plans against AMR;
- strengthen surveillance and monitor AMR and antimicrobial consumption;
- improve infection prevention and control - in particular via the health and welfare of food-producing animals to reduce the spread of infectious diseases in farms;
- ensure prudent use of antimicrobials;
- reduce the use of antimicrobials by 2030 by 20% in terms of total human consumption of antibiotics and by 50% in terms of total sales of antimicrobials used in the EU for farm animals and aquaculture;
- raise awareness, educate and train the public and professionals in the human and veterinary health sectors. ■

Sarah Faircliffe
Legal Director in Bird & Bird (London) LLP.

As a member of our International Life Sciences Group, I specialise in European regulatory law concerning medicinal products, medical devices and related areas. Bringing a wealth of industry and policy knowledge to my role here at Bird & Bird, I offer unique insight into the law and procedures concerning the regulation of medicines, having spent 10 years as Legal Adviser with the European Medicines Agency (EMA). During my time at the EMA, I advised on many areas, including orphan drugs, paediatrics and generics of centrally authorised products, as well as advising the EMA's scientific committees on legal issues.

Nour Saab
Life Sciences Lawyer - Bird & Bird

Johanna Harelimana

Junior associate, with experience advising clients on regulatory matters across several sectors, especially in life sciences, food and beverages, and environmental sectors. I currently offer both French and international clients legal advice on product's qualification, clinical trials, market access, price and reimbursement, anti-gift regulation, advertising and promotion, e-health (including telemedicine), as well as drafting contracts (distribution, professional services, clinical trial agreements, etc). I also assist with regulatory advice on other products such as cosmetics, biocide, phytopharmaceuticals and novel food.

1 HEALTH UNION: Identifying top 3 priority health threats, https://health.ec.europa.eu/system/files/2022-07/hera_factsheet_health-threat_mcm.pdf

2 Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020, https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf

3 For further developments on the Environmental Risk Assessment requirements under the proposed new Directive on medicinal products for human use, please read our article https://bio-talk.law/pharmaceuticals/strengthened-environmental-risk-assessment-requirements-under-the-proposed-new-directive-on-medicinal-products-for-human-use

Authors: **Emma Stok, Hester Borgers, Sarah Faircliffe**
Bird & Bird

Strengthened Environmental Risk Assessment requirements under the proposed new directive on medicinal products for human use

As part of the revision of the EU pharmaceutical legislative framework, a new directive on medicinal products for human use is proposed, which will repeal Directive 2001/83/EC.[1] One of the objectives of this proposed directive is to reduce the environmental impact of medicinal products. This proposal strengthens the requirements for the environmental risk assessment (ERA) and extends the scope of the ERA to cover new protection goals, including antimicrobial resistance.

Currently, Article 8(3)(g) of Directive 2001/83/EC only requires an environmental risk assessment to be submitted with the application for a marketing authorisation. The accompanying guidelines for the ERA describe how to assess the potential risks of the medicinal product to the environment and prescribe precautionary and safety measures to be considered if environmental risks cannot be excluded.[2] However, under Directive 2001/83/EC, the result of the ERA cannot be a reason to refuse the marketing authorisation.

The proposed directive would have far-reaching implications for the assessment of potential risks as part of the ERA and for its impact on the procedure for obtaining a market authorisation, but also for the period after the market authorisation is granted.

Under the proposed directive, a broader range of risks should be evaluated, including public health risks and antimicrobial resistance risks. Scientific guidelines to specify technical details regarding the ERA requirements will be drawn up by the European Medicines Agency.[3] With regard to antimicrobial medicinal products, the ERA should specify whether the product or any of its components are antimicrobial and include an evaluation of the risk of antimicrobial resistance selection as a result of the manufacture, use and disposal of the medicinal product.

Information on risk mitigation measures to limit the development of antimicrobial resistance associated with the use, prescription and administration of the medicine should also be included in the application for market authorisation.

Conducting an ERA is still part of the dossier requirements when applying for a marketing authorisation, but unlike in the current Directive 2001/83/EC, failure to include a sufficient risk assessment or sufficient risk mitigation measures will lead to the refusal of the marketing authorisation application.[4] For generic medicinal products or biosimilars, the marketing authorisation applicant may refer to studies conducted for the reference medicinal product when preparing the ERA.[5]

Moreover, instead of a one-off assessment, the ERA requirements will become an ongoing responsibility and will also apply to already authorised medicinal products. A marketing authorisation holder should, without undue delay, update the ERA with new information to the relevant competent authorities if new information becomes available that may lead to different conclusions of the ERA.[6] For ERAs conducted more than 18 months before the entry into force of the proposed directive, the marketing authorisation holder will be asked to update the ERA if missing information has been identified. For medicinal products authorised before 30 October 2005 that were not subject to an ERA and have been identified as potentially harmful to the environment, an ERA programme will be established.[7] ■

Emma Stok

As an associate in our Intellectual Property Group in The Hague, I offer our clients an all-round IP practice. Within our Intellectual Property Group, I advise and litigate on all areas of Intellectual Property, including patent, trade marks, trade names, product design and copyright matters. I have a special interest in both life sciences and the food industry. As part of our Life Science Regulatory group, I have contributed to international knowledge projects informing our clients of the latest regulatory developments.

Hester Borgers

As an associate in our Intellectual Property Group in Amsterdam, I specialise in patent law and life sciences regulatory and bring my passion for technology to the fore when I'm advising our clients on their matters. My experience includes patent litigation and regulatory advice, the latter focused on both the life sciences industry as well as the food industry. As a member of Bird & Bird's Life Sciences and Healthcare Group, I work daily on complex cross-country cases together with our other offices. I have experience in complex patent litigation, with a strong focus on the medical devices industry and pharmaceutical sector. Furthermore, I assist a broad range of life sciences clients with their regulatory matters, including litigation. My regulatory experience also includes advising with regard to all things digital health - from telemedicine to AI.

Sarah Faircliffe

Legal Director in Bird & Bird (London) LLP.

As a member of our International Life Sciences Group, I specialise in European regulatory law concerning medicinal products, medical devices and related areas. Bringing a wealth of industry and policy knowledge to my role here at Bird & Bird, I offer unique insight into the law and procedures concerning the regulation of medicines, having spent 10 years as Legal Adviser with the European Medicines Agency (EMA). During my time at the EMA, I advised on many areas, including orphan drugs, paediatrics and generics of centrally authorised products, as well as advising the EMA's scientific committees on legal issues.

1 Proposal for a directive of the European parliament and of the council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, 2023/0132/COD.
2 Guideline on the environmental risk assessment of medicinal products for human use, EMEA/CHMP/SWP/4447/00 corr 2.
3 Article 22 (5) proposed Directive.
4 Article 47 (1)(d) proposed Directive.
5 Article 22 (7) proposed Directive.
6 Article 22 (6) proposed Directive.
7 Article 23 (1) proposed Directive.

PDA
Parenteral Drug Association
CONNECTING PEOPLE SCIENCE AND REGULATION®

2023 PDA
UNIVERSE OF PRE-FILLED SYRINGES AND INJECTION DEVICES CONFERENCE

17-18 OCTOBER 2023
GOTHENBURG, SWEDEN
EXHIBITION: 17-18 OCTOBER 2023
WORKSHOPS: 16 OCTOBER 2023
TRAININGS: 19-20 OCTOBER 2023
PDA.ORG/EU/2023UPS

CHECK OUT THE WEBSITE AND REGISTER NOW!

PDA
Parenteral Drug Association
CONNECTING PEOPLE SCIENCE AND REGULATION®

2023 PDA
QUALITY AND REGULATIONS CONFERENCE

CHECK OUT THE WEBSITE AND REGISTER NOW!

07-08 NOVEMBER 2023
ANTWERP | BELGIUM

The Home of Translation

The specialist translation partner
for all your language needs

To get your message around the globe, you need a partner you can trust

25 years' experience of translating for the pharmaceutical industry.

At the Home of Translation, we provide global translation services for key players in the pharmaceutical industry, guaranteeing quality, efficiency and professionalism every time.

Our clients trust us to deliver translations in over 50 languages.

A comprehensive range of specialist services to meet your needs.

- Translating
- Interpreting
- Subtitling
- Voiceovers
- Proofreading
- Copywriting
- DTP
- Consultancy

www.home-of-translation.com
contact@home-of-translation.com

Offices in Paris, Lyon, Bordeaux and Munich

96 rue de la Roquette
75011 Paris FRANCE

45 rue Edouard Herriot
69002 Lyon FRANCE

26 rue Elisée Reclus
33000 Bordeaux FRANCE

Flurstraße 17, 86559 Adelzhausen
Munich GERMANY

BIO-EUROPE®

NOVEMBER 6–8, 2023 | MUNICH, GERMANY

Your gateway to the global biopharma community

The 29th annual BIO-Europe will take place November 6–8, 2023 in Munich, Germany, and it will convene over 5,000 life science professionals representing more than 2,220 companies from over 60 countries. Attendees will take part in 27,000 one-to-one meetings over the course of the event.

bioeuropean.com

Produced by: EBD GROUP

In collaboration with: Bio Biotechnology Innovation Organization